FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3521–3540

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *January 7, 1952.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 3521, 3523, 3524, 3532; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3523–3525, 3532; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3523, 3524; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3535; cosmetic, actionable under the drug provisions of the Act, see No. 3532 (Regene No. 29).

978345—51

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3521. Misbranding of Oxylin antiseptic tablets and Nef-Tex tablets. U. S. v. Louis E. Evons (Drexel Laboratories), and Meredith Evons. Pleas of guilty. Fine of $350 against each defendant. (F. D. C. No. 30563. Sample Nos. 48797–K, 67509–K, 73621–K, 73946–K, 73947–K, 81007–K, 81107–K.)

INFORMATION FILED: April 17, 1951, Eastern District of Pennsylvania, against Louis E. Evons, trading as Drexel Laboratories, Drexel Hill, Pa., and Meredith Evons, manager.

ALLEGED VIOLATION: On or about April 29 and December 13, 1949, and February 7 and 14, March 3, and May 10, 1950, the defendants caused quantities of *Oxylin antiseptic tablets* and *Nef-Tex tablets* to be introduced and delivered for introduction into interstate commerce, at Upper Darby and Drexel Hill, Pa., for delivery to Newton, East Orange, Flemington, and Newark, N. J., Albany, N. Y., and Baltimore, Md.

Between February 12 and May 8, 1950, while a number of *Oxylin antiseptic tablets* were being held for sale at the Drexel Laboratories after shipment in interstate commerce from Camden, N. J., the defendants caused a number of the tablets to be repacked and relabeled, which acts resulted in the tablets being misbranded.

NATURE OF CHARGE: *Oxylin antiseptic tablets.* Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article was an intestinal and urinary antiseptic; that it would be efficacious to arrest fermentation and allay irritation; and that it would be efficacious in the treatment of hyperacidity, intestinal toxemia, diarrhea, amebic and bacillary dysentery, bed wetting, gonorrhea, nephritis, pyelitis, cystitis, pyuria, intestinal grippe, influenza, and the common cold. The article was not an intestinal and urinary antiseptic, and it would not be efficacious for the purposes represented. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients; and it failed to bear a label containing the common or usual name of each of the active ingredients since it contained boric acid as one of its active ingredients, and the label of the article failed to declare the presence of boric acid. Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Dosage: Adults, 3 tablets swallowed with water on an empty stomach, 3 or 4 times daily. In acute or stubborn cases increase dosage to three tablets every two hours. Children, one tablet, four times daily," since such use of the article may result in boric acid poisoning.

Nef-Tex tablets. Misbranding, Section 502 (a), certain statements in the labeling of the article, which included an accompanying brochure headed "Nef-Tex Tablets," were false and misleading. The statements represented and suggested that the article would be efficacious to inhibit bacteria, arrest fermentation, remove the cause of intestinal and urinary irritations, and give quick relief from grippe and the common cold. The article would not be efficacious for the purposes represented.

DISPOSITION: September 11, 1951. Pleas of guilty having been entered, the court imposed a fine of $350 against each defendant.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3522. Para Acetylamino Benzal Thiosemicarbazone tablets. U. S. v. 499,600 Tablets * * *. (F. D. C. No. 31153. Sample No. 27821–L.)

LIBEL FILED: May 31, 1951, Northern District of California.

ALLEGED SHIPMENT: On or about September 29, 1950, by Olivier Co., Inc., from New York, N. Y.

PRODUCT: 499,600 tablets of *Para Acetylamino Benzal Thiosemicarbazone tablets* in 2 drums at San Francisco, Calif., together with a number of accompanying leaflets entitled "Reference Manual 601 TB1–PSL The New Antituberculous Drug."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: August 10, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3523. Misbranding of sulfathiazole tablets. U. S. v. Garrell's Pharmacy, Marshall F. Garrell, and Frank E. Garrell. Pleas of guilty. Garrell's Pharmacy fined $200, Marshall F. Garrell $100, and Frank E. Garrell $200. (F. D. C. No. 31095. Sample Nos. 25251–L to 25253–L, incl.)

INFORMATION FILED: June 21, 1951, Eastern District of Pennsylvania, against the Garrell's Pharmacy, a partnership, Philadelphia, Pa., and Marshall F. Garrell and Frank E. Garrell, partners in the partnership.

INTERSTATE SHIPMENT: From the State of New Jersey into the State of Pennsylvania, of quantities of sulfathiazole tablets.

ALLEGED VIOLATION: On or about January 9, 15, and 22, 1951, while the drug was being held for sale at Garrell's Pharmacy after shipment in interstate commerce, various quantities of the drug were repacked and sold without a prescription, which acts resulted in the repackaged drug being misbranded.

Garrell's Pharmacy was charged with causing the acts of repacking and sale of the drug involved in each of the 3 counts of the information; Marshall F. Garrell, in 1 count; and Frank E. Garrell, in 2 counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and a portion of the repackaged tablets bore no label containing a statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use since the directions "1 of each every 4 hours" borne on the labeling of the tablets were not adequate directions for use.

DISPOSITION: September 11, 1951. Pleas of guilty having been entered, the court imposed a fine of $200 against the partnership, $100 against Marshall F. Garrell, and $200 against Frank E. Garrell.

3524. Misbranding of radium chloride solution. U. S. v. 1 Ampul, etc. (F. D. C. No. 31311. Sample No. 13618–L.)

LIBEL FILED: July 3, 1951, District of Colorado.

ALLEGED SHIPMENT: On or about June 1, 1951, by the United States Radium Corp., from New York, N. Y.

PRODUCT: 1 unlabeled ampul of *radium chloride solution* at Denver, Colo., in the possession of the Denver Radium Corp., together with quantities of a booklet entitled "Radium Therapeutics" and folders entitled "Radium and High Blood Pressure," "New and Non Official Remedies," and "Modified Radium."

In a "Certificate of Analysis" which was sent by the shipper to the consignee, the product was represented to contain 1.06±.02 milligrams of radium.

RESULTS OF INVESTIGATION: After receipt, the consignee diluted the product with 40 cc. of salt solution and stored the mixture with the intention of placing it into ampuls for distribution. In addition, the consignee prepared the printed matter described above and used it in promoting the sale of the product.

NATURE OF CHARGE: Misbranding of the article before dilution, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the labeling of the article failed to bear adequate directions for use and such adequate warnings against unsafe dosage or methods or duration of administration or application in such manner and form as are necessary for the protection of users. The article before dilution was misbranded in the above respects when introduced into and while in interstate commerce.

Misbranding of the article after dilution, Section 502 (a), certain statements in the above-named booklet and folders accompanying the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for pernicious and secondary anemia, hypertension, myocardial affections, chronic articular and muscular rheumatism, insomnia, neuralgia, neuritis, neurasthenia, gout and similar disorders, chronic bronchial affections, gastric and duodenal ulcers, hay fever, lumbago, malnutrition, prostatitis, cystitis, sciatica, arthritis deformans, cardiovascular degeneration, endocarditis, vaginal and cervical disorders, recurrent uterus carcinoma, dysmenorrhea, fibroid tymors-sub-mucous (*sic*), nontubercular ulcers of the bladder, nephritis, urethritis, syphilis, hypertrophy of the thyroid, toxic and exophthalmic goiter, cataract (early stage), multiple sclerosis, arteriosclerosis, derangements of the circulatory, glandular, and nervous systems, Raynaud's disease, stricture, hypertrophic prostate, diseases of the kidneys and genito-urinary system, endometritis, low blood pressure evidenced by a deficiency in blood count of red corpuscles, thinness of blood and resultant low tension, chronic inflammatory conditions in general, and almost all of the ills the human body is heir to. The article was not an adequate and effective treatment for such symptoms, diseases, and conditions. The article after dilution was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: August 22, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

3525. Misbranding of epsom salt. U. S. v. 3 Bags, etc. (F. D. C. No. 30374. Sample No. 13766–K.)

LIBEL FILED: January 10, 1951, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 3, 1950, by the Dow Chemical Co., from Midland, Mich., to Philadelphia, Pa.

PRODUCT: 3 100-pound bags and 72 8-ounce and 72 1-pound packages of *epsom salt* at York, Pa., in possession of the Morris Drug Co.

RESULTS OF INVESTIGATION: The article was shipped in 100-pound bags from Midland, Mich., to Philadelphia, Pa., and subsequently a number of bags were resold to the Morris Drug Co., York, Pa. and were relabeled.

LABEL, IN PART: (Bag) "Dow Epsom Salt U. S. P. Recrystallized * * * The Dow Chemical Company, Midland, Michigan"; (package) "Epsom Salt Dose—From one teaspoonful to one tablespoonful in water. Morris Drug Company * * * York, Penna."

NATURE OF CHARGE: Misbranding (bags and packages), Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings as are necessary for the protection of users since it failed to warn that frequent or continued use of the article may result in dependence on laxatives to move the bowels, and that it should not be used when abdominal pain, nausea, vomiting, or other symptoms of appendicitis are present. The article was misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding (packages), Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents since its label contained no declaration of the quantity of the contents. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: August 1, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3526. Adulteration and misbranding of allyl isopropyl barbiturate sodium capsules. U. S. v. 20,000 Capsules * * *. (F. D. C. No. 31436. Sample No. 11182–L.)

LIBEL FILED: July 18, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about June 26, 1951, by the Diacin Chemical Co., from Detroit, Mich.

PRODUCT: 20,000 capsules of *allyl isopropyl barbiturate sodium* at Cleveland, Ohio. Examination showed that the product contained not more than 1.17 grains of allyl isopropyl barbiturate sodium per capsule.

LABEL, IN PART: "Each capsule contains allyl isopropyl barbiturate sodium 1½ Gr."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Each capsule contains allyl isopropyl barbiturate sodium 1½ Gr." was false and misleading as applied to an article containing not more than 1.17 grains of allyl isopropyl barbiturate sodium per capsule.

DISPOSITION: August 21, 1951. Default decree of condemnation and destruction.

3527. Adulteration and misbranding of pentobarbital sodium (powder). U. S. v. 4 Canisters * * *. (F. D. C. No. 30844. Sample No. 86313–K.)

LIBEL FILED: February 20, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about August 25, 1950, by B. L. Lemke & Co., Inc., from Lodi, N. J.

PRODUCT: 4 5-pound canisters of *pentobarbital sodium* (powder) at Los Angeles, Calif. Examination showed that the product contained not more than 97.5% pentobarbital sodium, calculated on the anhydrous basis, whereas the United States Pharmacopeia provides that the drug contain not less than 98.5% of pentobarbital sodium so calculated.

LABEL, IN PART: "Pentobarbital Sodium U. S. P. XIII."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Pentobarbital Sodium," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality and purity fell below, the official standard since the article contained a lesser proportion of pentobarbital sodium and a greater proportion of impurities than permitted by the official compendium.

Misbranding, Section 502 (a), the label statement "Pentobarbital Sodium U. S. P. XIII" was false and misleading as applied to an article which did not conform to the requirements of the U. S. P. XIII.

DISPOSITION: September 6, 1951. B. L. Lemke & Co., Inc., claimant having entered into a stipulation with the Government agreeing to the entry of a decree providing for the destruction of the product, judgment was entered ordering that the product be destroyed.

3528. Adulteration and misbranding of Cogenat (conjugated estrogens). U. S. v. 9,200 Tablets, etc. (F. D. C. No. 31336. Sample Nos. 17456–L, 17457–L.)

LIBEL FILED: July 10, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about September 6, 1950, and other unknown dates, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: *Cogenat* (conjugated estrogens). 9,200 tablets in 74 bottles and 11,700 tablets in 90 bottles at Los Angeles, Calif.

Analysis showed that the 74-bottle lot contained a total amount of estrogenic steroids calculated as 0.65 mg. of sodium estrone sulfate per tablet and that the 90-bottle lot contained a total amount of estrogenic steroids calculated as 0.35 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Cogenat * * * Conjugated Estrogens."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article in the two lots differed from that which it was represented to possess, namely, 1.25 mg. and 0.625 mg., respectively, of conjugated estrogens (equine) per tablet expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statements "Each tablet contains: Conjugated Estrogens (Equine) 1.25 mg. [or "0.625 mg."] expressed as Sodium Estrone Sulfate" were false and misleading as applied to an article which contained less than the stated amounts, respectively, per tablet of the total estrogenic steroids calculated as sodium estrone sulfate.

DISPOSITION: August 2, 1951. Default decree of condemnation and destruction.

3529. Adulteration and misbranding of conjugated estrogens. U. S. v. 5 Bottles * * *. (F. D. C. No. 30949. Sample No. 6874-L.)

LIBEL FILED: May 8, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about April 9, 1951, from Pittsburgh, Pa. This was a return shipment.

PRODUCT: 5 1,000-tablet bottles of *conjugated estrogens* at New York, N. Y. Examination showed that the total amount of estrogens actually present per tablet calculated to 0.69 mg., expressed as a mixture of sodium estrone sulfate and sodium equilin sulfate.

LABEL, IN PART: "Tablets Water Soluble Conjugated Estrogens * * * Robin Pharmacal Corp. New York, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mgm. of estrogens in their water-soluble form, expressed as sodium estrone sulfate and sodium equilin sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 Mgm. of estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate and sodium equilin sulfate" was false and misleading as applied to an article which contained a total amount of estrogens per tablet which calculated to 0.69 milligrams of a mixture of sodium estrone sulfate and sodium equilin sulfate.

DISPOSITION: July 31, 1951. The libel proceedings in the instant case having been removed to the Eastern District of New York and having been consolidated with two other cases relating to the same product, and International Hormones, Inc., Brooklyn, N. Y., claimant, having consented to the entry of a consolidated decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling of the containers, crushing of the tablets, and extraction of the hormones, with subsequent relabeling to insure compliance with the law.

3530. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Bottle * * *. (F. D. C. No. 30769. Sample No. 23102-L.)

LIBEL FILED: March 13, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about December 29, 1950, by Success Chemical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 1 1,000-tablet bottle of *conjugated estrogens* at Bloomfield, N. J. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.74 mg. of sodium estrone sulfate per tablet.

RESULTS OF INVESTIGATION: According to the consignee, the bottle of *conjugated estrogens* was damaged when received, and the product was transferred by him to another bottle labeled "Premarin Tablets."

LABEL, IN PART: (Bottle, when shipped) "Tablets Conjugens (Conjugated Estrogens) 1.25 mg. Distributed by Success Chemical Co., Inc., Brooklyn, N. Y."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely 1.25 mg. of estrogens in their naturally occurring water-soluble conjugated form, expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the statement which appeared on the bottle label when shipped, namely, "Each tablet contains 1.25 mgm. of Estrogens in

their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained less than the stated amount of estrogens.

DISPOSITION: July 11, 1951. Default decree of condemnation and destruction.

3531. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Bottle, etc. (and 1 other seizure action). (F. D. C. Nos. 30926, 30927. Sample Nos. 24518–L, 24519–L.)

LIBEL FILED: April 17 and 19, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about February 5 and March 5, 1951, by Steroid Laboratories, Ltd., from Montreal, Canada, to Brooklyn, N. Y. A portion of the product had been relabeled by the Brooklyn consignee and had been shipped from Brooklyn, N. Y., to New York, N. Y.

PRODUCT: *Conjugated estrogens.* 2 tins, each containing 2 kilograms, at Brooklyn, N. Y.; and 1 tin containing 2 kilograms and 1 bottle containing 1,150 grams at New York, N. Y. Examination showed that the article contained not more than 20 milligrams of total estrogens per gram.

LABEL, IN PART: (Tin, when shipped from Canada) "Conjugated Estrogens (Equine) Powder. Each gram contains 27.8 mg. estrogens"; (tin and bottle, relabeled portion) "Conjugated Water Soluble Estrogens. Each gram contains 27.8 mg. estrogens."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 27.8 mg. estrogens per gram.

Misbranding, Section 502 (a), the label statement "Each gram contains 27.8 mg. estrogens as determined by Squibb modification of Kober Test" was misleading as applied to an article which contained not more than 20 mg. of total estrogens per gram.

The portion of the product at New York, N. Y., was adulterated and misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: July 31, 1951. The libel proceedings in the New York case having been removed to the Eastern District of New York and consolidated with the Brooklyn case and another case involving another lot of the same product, and International Hormones, Inc., Brooklyn, N. Y., having consented to the entry of a consolidated decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling of the containers, crushing of the tablets, and extraction of the hormones, with subsequent relabeling to insure compliance with the law.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE *

3532. Misbranding of Alcorine No. 28, Barrab No. 26, and Regene No. 29. U. S. v. Jerome Barnes (Barnes Co.). Plea of guilty. Fine of $150 and probation for 1 year. (F. D. C. No. 30565. Sample Nos. 60495–K, 75607–K, 77320–K.)

INFORMATION FILED: June 11, 1951, Eastern District of Virginia, against Jerome Barnes, trading as the Barnes Co., Portsmouth, Va.

*See also Nos. 3521, 3524, 3526–3531.

ALLEGED SHIPMENT: On or about January 28, February 20, and April 29, 1950, from the State of Virginia, into the States of Indiana, Illinois, and Wisconsin.

PRODUCT: Examination disclosed that the *Alcorine No. 28* was essentially an acidulated dilute solution of a sugar; that the *Barrab No. 26* consisted of gelatin capsules containing wheat germ oil; and that the *Regene No. 29* was essentially perfumed petrolatum.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles, which included certain accompanying circulars, were false and misleading. The statements represented and suggested that the *Alcorine No. 28* would be efficacious in the treatment of drunkenness and that it would be efficacious to tone up the nervous and digestive systems; that the *Barrab No. 26* would be efficacious to increase personal energy, to develop power, to give a firmer, fuller, more youthful grip on life, to relieve that helpless incapable feeling, and to give a stronger, more vigorous nature, and that it would be efficacious to increase stamina and energy and to enable a person to make the most of his or her sexual powers; and that the *Regene No. 29* would be efficacious as a treatment for baldness and other scalp disorders, and that it would be efficacious to revitalize the scalp, correct local disorders, purge out infectious germs, penetrate the tissues and kill hair-destroying germs, overcome complex dandruff, and normalize excess dryness or oiliness. The articles would not be efficacious for the purposes represented.

Further misbranding, Section 502 (b) (2), the labels of the articles failed to bear statements of the quantity of the contents; and, Section 502 (e) (1), the *Barrab No. 26* failed to bear a label containing the common or usual name of the drug, namely, wheat germ oil.

DISPOSITION: July 18, 1951. A plea of guilty having been entered, the court imposed a fine of $150 and placed the defendant on probation for 1 year.

3533. Misbranding of Champion Compound. U. S. v. 360 Bottles, etc. (F. D. C. No. 31624. Sample No. 31116–L.)

LIBEL FILED: August 16, 1951, Western District of Tennessee.

ALLEGED SHIPMENT: On or about June 19, 1951, by the Cel-Ton-Sa Medicine Co., from Cincinnati, Ohio.

PRODUCT: 360 16-ounce bottles of *Champion Compound* at Memphis, Tenn., together with a number of accompanying circulars entitled "Leading The Way To Improved Internal Hygiene."

Analysis showed that the product was an aqueous liquid containing extracts of plant drugs, including laxative drugs, an iron compound, and aromatics.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circulars were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for general digestive disorders, minor stomach disorders, rheumatism, dropsical [*sic*], kidney and bladder ailments of a minor nature, incipient catarrh of the bladder, and gravel; that the article was a blood conditioner; that it contained therapeutically significant amounts of vitamins and minerals; and that it was effective in maintaining or restoring the health of the user. The article would not be effective for such purposes.

DISPOSITION: October 2, 1951. Default decree of condemnation and destruction.

3534. Misbranding of Kennedy's Mixture. U. S. v. 3 Cases * * *. (F. D. C. No. 31183. Sample Nos. 917–L, 918–L.)

LIBEL FILED: June 8, 1951, Western District of North Carolina.

ALLEGED SHIPMENT: On or about April 30 and May 14, 1951, by the York Drug Store, from York, S. C.

PRODUCT: 3 cases, each containing 36 8-ounce bottles of *Kennedy's Mixture* at Charlotte, N. C.

LABEL, IN PART: (Bottle) "Kennedy's Mixture Active Ingredients: Sodium Citrate and Bismuth Subnitrate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article, namely, in the form letter wrapped around each bottle, were false and misleading since the article was not effective in the treatment of the conditions stated and implied and would not fulfill the other promises of benefit made for it: "also for irritated and ulcerated conditions of the stomach and duodenal tract. I firmly believe that if it is taken regularly, the inner lining of the stomach will get a protective coating which will help wonderfully towards a return to normal conditions. * * * Good health is a great blessing, so make an effort to restore it * * *."

DISPOSITION: July 12, 1951. Default decree of condemnation and destruction.

3535. Misbranding of Domogyn vaginal douche powder. U. S. v. 79 Cans, etc. (F. D. C. No. 30936. Sample Nos. 9718–L, 9723–L, 9724–L.)

LIBEL FILED: May 1, 1951, Northern District of Illinois; libel amended on or about May 25, 1951.

ALLEGED SHIPMENT: Between the approximate dates of January 12 and April 24, 1951, by Dome Chemicals, Inc., from New York, N. Y.

PRODUCT: 79 1-pound cans and 64 4-ounce cans of *Domogyn vaginal douche powder* at Chicago, Ill. Analysis indicated that the product consisted essentially of aluminum sulfate, calcium acetate, boric acid, starch, and a wetting agent.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "therapeutic douche for * * * leukorrhea and common forms of vaginitis" was false and misleading since the article was not effective in the treatment of these conditions; and, Section 502 (c), the information required by Section 502 (e) (2) to appear on the label, namely, the common or usual names of the active ingredients, was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices) as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use since it appeared in very small type, part of which was on each of two side panels of the label.

DISPOSITION: July 31, 1951. Default decree of condemnation and destruction.

3536. Misbranding of ozone generators. U. S. v. 17 Devices, etc. (F. D. C. No. 31329. Sample Nos. 12797–L, 12805–L.)

LIBEL FILED: July 9, 1951, District of New Mexico.

ALLEGED SHIPMENT: On or about April 11 and 25, 1951, by A. F. Peavey, from Tucson, Ariz.

PRODUCT: 17 *ozone generators* at Albuquerque, N. Mex., together with a number of folders entitled "Bulletin 11" and "Bulletin 12" and a number of sales manuals entitled "Dr. O. M. Justice."

The device consisted of 8 tubes, 4 of which fluoresce blue and 4 of which fluoresce orange when activated by an electric current, together with the electrical mechanism to activate the tubes.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying folders and sales manuals were false and misleading. The statements represented and suggested that the ozone produced by the device protects from air-transmitted disease, neutralizes carbon monoxide, increases the oxyhemoglobin in the blood, rids the body of disease, and restores vitality, strength, health, and vigor; and that the device was effective in the treatment of anemia, asthma, arthritis, all diseases of the respiratory organs, bronchitis, catarrh, chlorosis, colds, colibacillosis, constipation, corns, cramps in legs, feet, and arms, dyspepsia, eczema, fatty tumors, fistula, gall bladder trouble, gas poisoning, hay fever, headache, heart trouble, hemorrhoids, influenza, insomnia, inactive liver, inactive kidneys, liver spots, migraine, melancholia, mucous colitis, neurasthenia, nerves, osteomyelitis, paralysis of the face, disorders of the prostate, psoriasis, rheumatic pains, sinusitis, syphilis in any stage, tuberculosis, varicose veins, whooping cough, and many other ailments. The device was not capable of fulfilling the promises of benefit made for it, and it was not effective in the treatment of the diseases stated and implied.

DISPOSITION: September 4, 1951. Default decree of condemnation. The court ordered that the devices be turned over to the Food and Drug Administration.

3537. Misbranding of ultraviolet lamps. U. S. v. 2 Devices * * *. (F. D. C. No. 30398. Sample No. 24491–L.)

LIBEL FILED: January 24, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about October 20, 1950, by Sun-Kraft, Inc., from Chicago, Ill.

PRODUCT: 2 *ultraviolet lamps* at Jamaica, N. Y. Examination of the device showed that it consisted of a cold-quartz type lamp mounted on a metallic base and equipped with a timing mechanism. Examination indicated further that the lamp would emit ultraviolet radiations of a comparatively low intensity.

LABEL, IN PART: "Sun-Kraft Cold-Quartz Ultra-Violet and Ozone Apparatus."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying booklet entitled "How to Use Your Sun-Kraft" were false and misleading. The statements represented and suggested that the device was an adequate treatment for many different types of skin diseases, such as acne, psoriasis, many varieties of eczema, scalp conditions, and skin tuberculosis, and for skin ulcers and slow healing wounds. The device was not an adequate treatment for such conditions.

DISPOSITION: August 21, 1951. Default decree of condemnation and destruction.

3538. Misbranding of O. R. O. U. S. v. 47 Bottles, etc. (F. D. C. No. 31322. Sample No. 15988–L.)

LIBEL FILED: July 3, 1951, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about March 6, 1951, by O. O. Roberts, from Fort Worth, Tex.

PRODUCT: 47 bottles of *O. R. O.* at Lawton, Okla., together with a number of circulars entitled "O. R. O." Analysis showed that the product was a lime and sulfur solution.

LABEL, IN PART: (Bottle) "6 Ozs. or Over O. R. O. 14% light sulphur 2% hydrated lime 84% water (inert)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the accompanying circulars were false and misleading. The statements represented and suggested that the article was effective in the treatment of unspecified diseases of poultry, running fits, mange, and other skin diseases of dogs, and coccidiosis and sorehead in chickens, turkeys, etc.; that it was effective to remove worms from poultry, hogs, dogs, or livestock of any kind; that it was effective to eliminate blue bugs and fleas on chickens and turkeys; and that it was effective in the treatment of poison ivy, prickly heat, ringworm, itchy scalp, scaly skin, chafed skin, rash, etc., of humans. The article was not effective for such purposes.

DISPOSITION: August 13, 1951. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE *

3539. Misbranding of Dr. Jelen's Liquid Hog Medicine. U. S. v. 3 Pails, etc. (F. D. C. No. 31172. Sample No. 18916–L.)

LIBEL FILED: June 7, 1951. District of Minnesota.

ALLEGED SHIPMENT: On or about April 5, 1951, by Dr. Jelen's Veterinary Supply Corp., from Omaha, Nebr.

PRODUCT: 3 2-gallon pails and 5 1-gallon jugs of *Dr. Jelen's Liquid Hog Medicine* at New Ulm, Minn., together with a number of accompanying pamphlets entitled "Customer's Price List April 1950."

Examination indicated that the product consisted essentially of potassium arsenite, sodium hydroxide, sodium carbonate, sodium thiosulfate, sodium phosphate, potassium iodide (trace), creosote, anise oil, and licorice extract. Niacin (nicotinic acid) may have been present in the product but was not determined by analysis.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying pamphlets were false and misleading. The statements represented and suggested that the article would aid in the treatment of necrotic enteritis ("necro"), and black scours; that it was helpful as a tonic in such cases; that it was a valuable aid in the feeding of poultry; that it would help one to keep his herd in better condition and free from "necro" at all times; and that it would help to keep the brood sow in good condition and to produce litters free from "necro." The article was not effective for the purposes stated and implied, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: July 27, 1951. Default decree of destruction.

3540. Misbranding of Dr. Mayfield poultry tablets. U. S. v. 23 Bottles, etc. (F. D. C. No. 29345. Sample Nos. 76130–K, 76131–K.)

LIBEL FILED: June 3, 1950, District of Minnesota.

ALLEGED SHIPMENT: On or about March 30 and April 12 and 27, 1950, by Dr. Mayfield Laboratories, Inc., from Charles City, Iowa.

*See also No. 3538.

PRODUCT: 23 1,000-tablet bottles and 39 500-tablet bottles of *Dr. Mayfield poultry tablets* at Sleepy Eye, Minn., together with a number of cards entitled "Poultry Disease Prevention Program" and a number of circulars entitled "Dr. Mayfield Poultry Tablets for Coccidiosis Control."

LABEL, IN PART: (Bottle) "Dr. Mayfield Poultry Tablets * * * Active Ingredients: Sodium Arsanilate (.35 grains arsenic per tablet expressed as metallic) Ammonium Phenolsulphonate and Boric Acid are therapeutically inactive."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and on the cards and circulars accompanying the article were false and misleading since the statements represented and suggested that the article was effective in the prevention and treatment of blackhead in turkeys and in the prevention of disease conditions of poultry when used as directed, whereas the article was not effective for the purposes stated and implied.

DISPOSITION: September 24, 1951. Dr. Mayfield Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Federal Security Agency.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3541–3549

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting on reports submitted by the Federal Security Agency. This is a collection of cases adjudicated earlier than those now being recorded in current notices of judgment, but not published because complete records were not available immediately after the cases were terminated. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *February 14, 1952.*

CONTENTS

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3541. Misbranding of Sulfa Salverol ointment. U. S. v. 8,148 Tubes * * *. (F. D. C. No. 15287. Sample No. 6315–H.)

LIBEL FILED: February 19, 1945, Southern District of New York.

ALLEGED SHIPMENT: On or about July 10 and 17 and August 9, 1944, from Newark, N. J., by Day Chemical Co., Inc.

PRODUCT: 8,148 tubes of *Sulfa Salverol ointment* at New York, N. Y.

LABEL, IN PART: "Contains: Sulfanilamide 4%, Sulfathiazole 3%, with Oil of Cade, Calamine, and Menthol combined in a specially Prepared absorption base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying circular entitled "New Sulfa Formula Works Wonders on the Home Front!" were false and misleading. The statements represented and suggested that the article was effective as a remedy in many stubborn skin diseases; that it would permit natural healing; and that it would be efficacious in the treatment of eczema, dermatitis, athlete's foot, acne, psoriasis, skin rashes, pimples, scabies, scalp seborrhea, sores, barber's itch, insect bites, abrasions, cuts, and minor burns. The article was not an adequate treatment for the conditions mentioned, and it would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe dosage and methods and duration of administration or application since there were no warnings to the effect that the article may produce a sensitivity to sulfonamides, preventing their subsequent use in serious conditions for which those drugs could have been life-saving, or that the article should not be used on persons with known sensitivity to the sulfonamides.

Section 505 (a), the article was a new drug within the meaning of the law, and no application filed pursuant to the law was, or had been, effective with respect to the article.

DISPOSITION: March 2, 1945. The Research Drug Co., Inc., New York, N. Y., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3542. Action to enjoin and restrain the interstate shipment of misbranded Gingisol. U. S. v. David J. Barben (Gingisol Laboratories). (Inj. No. 196.)

COMPLAINT FILED: June 28, 1948, Northern District of Ohio, against David J. Barben, trading as Gingisol Laboratories, Cleveland, Ohio.

NATURE OF CHARGE: That the defendant had been and was at the time of filing the complaint introducing and causing the introduction into interstate commerce, at Cleveland, Ohio, consignments of a drug designated as *Gingisol*, consisting of a solution of phenol and alkali in flavored, perfumed, colored water;

* See also No. 3541.

that in some instances, the drug when introduced into interstate commerce, was misbranded under Section 502 (a), in that the labeling contained statements which represented and suggested that the drug would be efficacious in the cure, mitigation, treatment and prevention of gingivitis and pyorrhea; would be efficacious to restore soft, spongy, bleeding gums to a healthy pink color, and would help keep gums firm and healthy; would cause swelling, bleeding, and tenderness in gums to subside; would aid materially in the healing process after tooth extractions; would be efficacious in the treatment of abscessed teeth, infected gums, and infected tonsils; would aid in the correction of the chief causes of rheumatism, heart trouble, kidney disorders, stomach trouble, and nervous disorders; and would prevent the absorption of germs and poisons developing in diseased teeth and in infected gums and tonsils; and that the said statements were false and misleading since the product would not be efficacious for the purposes represented, suggested, and implied.

The complaint alleged further that in some instances, the drug when introduced into interstate commerce, was misbranded under Section 502 (f) (1), in that the labeling failed to bear adequate directions for use in all conditions for which it was intended to be used and for which it was prescribed, recommended, or suggested in its advertising, disseminated or sponsored by or on behalf of the defendant, namely, bleeding gums, pyorrhea, loss of all teeth, soft, spongy, bleeding gums, and gingivitis.

The complaint alleged further that the defendant still continued to introduce into interstate commerce the drug which was misbranded as stated above, and alleged on information and belief that he would continue to do so unless restrained. The complaint prayed the entry of a decree perpetually enjoining the defendant from introducing the drug under the name *Gingisol*, or by any other designation or any similar drug, which was misbranded under Sections 502 (a) and 502 (f) (1), and that he be ordered to show cause why he should not be restrained from such acts during the pendency of the proceedings.

DISPOSITION: On December 17, 1948, the defendant having consented to the entry of a decree, the court entered an order perpetually enjoining and restraining the defendant and all persons acting upon his behalf from directly or indirectly introducing into interstate commerce the above-described drug under the designation *Gingisol*, or by any other designation or any similar drug, which was misbranded under Sections 502 (a) and 502 (f) (1). The decree contained the proviso that the defendant could introduce the drug, *Gingisol*, composed of a solution of potassium phenolate and a small proportion of fluorides, into interstate commerce under appropriate labeling so long as it was intended for use solely as a simple mouth wash for which no therapeutic claims were made.

3543. Misbranding of calcium polysulfide solution. U. S. v. Wilfred S. McKeon. Plea of guilty. Fine of $50, plus costs, on count 1; suspended sentence and probation for 2 years on count 2. (F. D. C. No. 24253. Sample Nos. 68292-H, 68293-H.)

INFORMATION FILED: April 19, 1948, Western District of Pennsylvania, against Wilfred S. McKeon.

INTERSTATE SHIPMENT: On or about February 26 and 27, 1947, from the State of Pennsylvania into the State of Kansas, of quantities of *calcium polysulfide solution*.

LABEL, IN PART: "Calcium Polysulphide Solution Active Ingredients: Calcium Polysulphide . . . 31% Calcium Thiosulphate . . . 1% Inert Ingredients . . . 68% Total Sulphur (At Least) . . . 24%."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the drug failed to bear adequate directions for use since the labeling contained no directions for use.

DISPOSITION: July 1, 1948. A plea of guilty having been entered, the court imposed a $50 fine, plus costs, on count 1 and suspended sentence and placed the defendant on probation for 2 years on count 2.

DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3544. Action to enjoin and restrain the interstate shipment of adulterated and misbranded rubber prophylactics. U. S. v. Joseph Lader, Clara Lader, and Anna Lader (Crown Rubber Sundries Co.). Permanent injunction granted. (Inj. No. 97.)

COMPLAINT FILED: On or about June 12, 1945, Northern District of Ohio, against Joseph Lader, Clara Lader, and Anna Lader, partners, trading under the name of the Crown Rubber Sundries Co., Akron, Ohio.

NATURE OF CHARGE: The complaint alleged that the defendants since about the month of July 1944 had been and were at the time of filing the complaint engaged in purchasing, packing, distributing, and selling, and introducing and causing to be introduced into interstate commerce, from Akron, Ohio, devices known as *rubber prophylactics* or condoms; that these devices were adulterated under Section 501 (c) since they consisted of defective, imperfect, and old material, and contained holes and defects and other imperfections, so that their strength differed from, and their quality fell below, that which they purported and were represented to possess; that the said devices were misbranded under Section 502 (a) in that they were recommended and labeled as suitable for the prevention of venereal disease, and the labeling was false and misleading since the devices were not suitable for such purposes, because of the presence of holes.

The complaint alleged further that a large number of shipments of *rubber prophylactics* by the defendants had been examined; that seizures had been instituted against many of the firm's consignments; that the defendants had been given notice on three occasions of contemplated criminal action; that Joseph Lader refused to permit inspection of the defendants' plant in December 1944, following the investigation of a shipment which had been found to consist of old, rejected stock; that on January 8 and 23, 1945, inspectors again were refused permission to inspect the premises; and that in 1945 a considerable number of the firm's interstate shipments again were sampled, and the examination showed the product to be from 12.5% to 33% defective.

The complaint alleged further that on March 24, 1945, notice again was given to the Crown Rubber Sundries Co. and Joseph Lader that opportunity would be afforded them to present their views with respect to contemplated criminal proceedings charging violation of the law; that statements made by Joseph Lader at a hearing on March 26, 1945, established that no tests were made by the firm in order to discover imperfections before shipment in interstate commerce; and that during inspections Joseph Lader had been informed of the imperfections found in the devices and had been warned

and advised not to ship such devices in interstate commerce, but that such warnings and advice had been unheeded.

The complaint alleged further, on information and belief, that the defendants would continue to violate the law unless restrained from so doing, and prayed the issuance of a decree perpetually enjoining and restraining the defendants from the acts complained of; and that a temporary restraining order issue immediately, granting the relief prayed for.

DISPOSITION: On August 22, 1945, a temporary restraining order was issued as prayed in the complaint. On April 7, 1948, the defendants having admitted the allegations of the complaint and consented to the entry of a decree, judgment was entered that the defendants, their agents, servants and employees, and all persons acting for or on their behalf, be perpetually enjoined and restrained from introducing or delivering for introduction into interstate commerce, directly or indirectly, devices which the defendants, at the time or at any time thereafter, may have in their possession or under their control, which are adulterated or misbranded as charged in the complaint.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3545. Action to enjoin and restrain the altering of labeling and unlawful acts with respect to vitamin products while held for sale after shipment in interstate commerce. U. S. v. Vitamin Store of Missouri and Louis E. Krawitz and Miriam W. Krawitz. Injunction granted. (Inj. No. 160.)

COMPLAINT FILED: April 14, 1947, Eastern District of Missouri, against the Vitamin Store of Missouri, a partnership, St. Louis, Mo., and Louis E. Krawitz and Miriam W. Krawitz, partners.

NATURE OF CHARGE: The complaint alleged that the defendants had been and were at the time of filing the complaint engaged in the retail sale of vitamin products which had been shipped in interstate commerce and held for sale by the defendants after such shipment; and that it was the usual and common practice to display and cause to be associated with each of the vitamin products certain printed and graphic circulars, posters, and pamphlets which represented the product to be effective in the treatment or prevention of various ailments and diseases, and which constituted labeling of such products.

The complaint alleged further that the defendants had received in interstate commerce vitamin products which were labeled and designated, in part, "Multi-B-Plex Tablets," "Super B-Plex Plus Tablets," "Vitamin C Tablets," "Vitamin A Capsules," "Vita-Slim," "Arthron Vitamin D," "Super Potency Pan-A-Plex," "Super-Complex Special Formula No. 10," "Aller-Cedic * * * Capsules," "Nura-Plex Capsules," and "Ultra-Beta Capsules," and that while these products were held for sale after shipment in interstate commerce, the defendants caused the pamphlets, posters, and circulars referred to above to be displayed and associated with the products, which resulted in the products becoming misbranded under Section 502 (a); that certain statements in the pamphlets and posters represented and suggested that the *Super B-Plex Plus tablets* were effective in the treatment or prevention of, or would aid persons suffering from, fatigue, nervousness, insomnia, neuritis, constipation, and loss of appetite; that certain statements in the circulars and posters represented and suggested that the *Multi-B-Plex tablets* were effective in the treat-

*See also Nos. 3541, 3542, 3544.

ment or prevention of, or would aid persons suffering from, fatigue, nervousness, insomnia, neuritis, constipation, and loss of appetite; that certain statements in the pamphlets represented and suggested that the *vitamin C tablets* were effective in the treatment or prevention of, or would aid persons suffering from, anemia, hemorrhages, swollen, bleeding gums, tooth cavities, loose teeth, poor wound healing, gastric ulcers, and asthma and hay fever of allergic origins; that certain statements in the pamphlets represented and suggested that the *Arthron vitamin D* was effective in the treatment of arthritis; that certain statements in the circulars and posters represented and suggested that the *vitamin A capsules* were effective in the treatment or prevention of, or would aid persons suffering from, itching, burning, and dryness of eyes, night blindness, decreased vision, dry and rough skin, sinus infection, tendency to colds and infections, colds, and sinusitis; that certain statements in the circulars and posters represented and suggested that the *Vita-Slim* was effective in reducing and preventing overweight; that certain statements in the pamphlets represented and suggested that the *Super Potency Pan-A-Plex* was effective in the restoration of hair color; that certain statements in the posters represented and suggested that the *Super-Complex Special Formula No. 10* was effective in the treatment or prevention of, or would aid persons suffering from, arthritic pains, neuritic pains, rheumatic pains, fatigue, listlessness and nervousness; that certain statements in the pamphlets represented and suggested that the *vitamin A capsules* were effective in the treatment or prevention of, or would aid persons suffering from, colds, infections, sinus, eye trouble, dry skin, and acne; that certain statements in the circulars and posters represented and suggested that the *Aller-Cedic * * * capsules* were effective in the treatment or prevention of, or would aid persons suffering from, hay fever, asthma, and food allergies; that certain statements in the pamphlets represented and suggested that the *Ultra-Beta capsules* were effective as a tonic builder for persons suffering from loss of pep, poor appetite, sleeplessness, constipation, nervousness, and depression, and were effective in the treatment or prevention of such ailments and conditions; that certain statements in the pamphlets represented and suggested that the *Super-Complex Special Formula No. 10* was effective in the treatment or prevention of, or would aid persons suffering from, arthritic pains, neuritic pains, rheumatic pains, constipation, fatigue, nervousness, insomnia, depression, and sciatica; and that certain statements in the pamphlets represented and suggested that the *Nura-Plex capsules* were effective in the treatment and prevention of, and would aid persons suffering from, nervousness, fatigue, constipation, neuritis, skin disorders, and nervous indigestion. The statements and representations contained in the pamphlets, circulars, and posters were false and misleading since the products were not effective in the treatment or prevention of, and would not aid persons suffering from, the conditions and ailments stated and implied.

The complaint alleged further that the defendants had been warned and notified of their acts of misbranding, but had disregarded the warnings and continued to make false and misleading representations concerning these vitamin products; and alleged also, on information and belief, that they would continue to do so.

The complaint prayed that a preliminary injunction be granted, restraining and enjoining the defendants from the acts complained of, and that the preliminary injunction be made permanent after due proceedings.

DISPOSITION: April 29, 1947. The defendants having consented to the entry of a decree, the court issued a temporary injunction which was to become effective on May 5, 1947.

The decree enjoined the defendants and all persons acting on their behalf from directly or indirectly altering the labeling of, or doing acts with respect to, drugs while they were held for sale after shipment in interstate commerce, which acts would result in such drugs being misbranded within the meaning of Section 502 (a); and from causing any written, printed, or graphic matter which is false or misleading in any particular to accompany any article of drug while such article was being held for sale after shipment in interstate commerce in violation of Section 301 (k); and, further, from doing any other act which would result in such article being misbranded within the meaning of Section 502 (a).

3546. Misbranding of Gold-Lax Tonic. U. S. v. Eijiro Ishii (Gold-Lax Tonic Laboratory). Plea of nolo contendere. Fine, $100, plus costs. (F. D. C. No. 21444. Sample Nos. 59860–H, 84844–K.)

INFORMATION FILED: August 27, 1947, Northern District of Ohio, against Eijiro Ishii, trading as the Gold-Lax Tonic Laboratory, Painesville, Ohio.

ALLEGED SHIPMENT: On or about April 14, 1946, and April 23, 1947, from the State of Ohio into the State of Pennsylvania.

LABEL, IN PART: (Bottle) "Ishii's Gold-Lax Genuine The active ingredient is senna pods. The article is recommended as a laxative for occasional constipation. Contains Asparagus, Beets, Carrots, Celery, Orange, Fennel Seeds, and Senna Pods."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Genuine Gold Lax Tonic" and "Genuine Ishii's Gold Lax Tonic" were false and misleading. These statements represented and suggested that the drug was a tonic; that it would be efficacious to prevent premature old age and death; that it would prevent a deficiency of minerals and vitamins, would prevent deposits of poisons and acids in the weakest areas of the body, would aid digestion of foods and assimilation of minerals, would be of benefit to diabetic sufferers, would create energy, would aid the body to secrete insulin, would remove impurities, would build up resistance and restore energy, pep, and stamina, would enable the user to be pure within and without, and would correct stomach trouble and enable the user to assimilate all elements; that it would be efficacious in the prevention and treatment of anemia, arthritis, asthma, diabetes, dropsy, female periodic complaint, heart ailment, high blood pressure, low blood pressure, liver trouble, kidney trouble, gall bladder trouble, pimples, pernicious anemia, psoriasis, rheumatism, shingles, swollen legs, streptococcus infection, tuberculosis, varicose ulcers, and colds; that it would aid in removing poisons from the intestines and kidneys, would improve the appetite, would supply necessary minerals, vitamins, and many other health giving foods, would improve the user's health, would settle the nerves and regulate the kidneys, and would prevent a feeling of tiredness in the morning and enable the user to sleep soundly at night; that it would be efficacious in the treatment of mucous trouble and bowel trouble and would enable the user to gain weight; that it would be efficacious in the treatment of constipation, tense nerve condition,

asthma, and gas conditions, and would enable the user to breathe easier; that it would be efficacious in the treatment of poor circulation and brittle fingernails, would enable the user to feel years younger, would insure a good appetite, heal running sores, and relieve tired feeling, would be efficacious to make hair grow, and would prevent drying of the skin, stop itching of the skin, and eliminate weak spells. The drug was not a tonic, and it would not be efficacious for the purposes represented and suggested.

DISPOSITION: January 19, 1948. A plea of nolo contendere having been entered, the court imposed a fine of $100, plus costs.

3547. Misbranding of StafTabs calcium and phosphorus tablets. U. S. v. 37 Bottles, etc. (F. D. C. No. 26103. Sample No. 14180–K.)

LIBEL FILED: December 16, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: The drug was shipped on or about October 4, 1948, by Modern Products, Inc., from Milwaukee, Wis. A number of circulars were shipped on or about July 14, 1948, by a bindery in Waltham, Mass., on instructions from Modern Products, Inc.

PRODUCT: 37 bottles of *StafTabs calcium and phosphorus tablets* at Chicago, Ill., together with 29 circulars entitled "Can Minerals Prevent Premature Aging."

LABEL, IN PART: (Bottle) "StafTabs Calcium and Phosphorus with Vitamin D Each tablet contains 188 milligrams Calcium, 95 milligrams Phosphorus, 100 U. S. P. Units Vitamin D, 2½ mgs. Iron, 0.025 mgs. Iodine Ingredients: Tricalcium Phosphate, Iodized Casein (Iodine derivative of an organic compound), Iron Peptonate, Vitamin D Concentrate from fish liver oil, Flavoring."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular were false and misleading. The statements represented and suggested that the drug would prevent premature aging, would give one health and zest for life, would keep the blood and tissue fluid from becoming too acid or too alkaline, would influence the secretion of the glands, would influence the sending of messages through the nervous system, would enable one to attain maximum vigor, would insure against poorly formed, soft, and porous bones and teeth, would prevent children from becoming stunted, would prevent adults from being high-strung, quick-tempered, grouchy, and irritable, and feeling tense and uneasy, would assure calmness and stability, conserving mental and physical nerves, would prevent insomnia and brooding during the night over the probable fatigue during the coming day, would increase efficiency, peace, and happiness in the family, would prevent abdominal cramps, extreme nervousness, mental depression, and headaches during menstruation, or would cause these symptoms to disappear, would prevent irritability, insomnia, and loss of teeth during change of life, would enable one to retain the good characteristics of youth through a longer stretch of adult life before signs of old age appear, would prevent nervousness, tiredness, suffering from insomnia, and resorting to artificial teeth, would promote normal heart reaction, nerve conduction, energy exchange in muscle contraction, and glandular functioning, would prevent a decrease of stamina, endurance, and general vitality, would maintain mental and physical efficiency and alertness, would prevent or remedy cases in which people "just don't feel too well," would effect powerfully the physical and mental development, and would give the body a normal verve and urge for work and play. The drug would not fulfill the promises of benefit stated and implied in the labeling.

DISPOSITION: January 12, 1949. Default decree of condemnation and destruction.

3548. Misbranding of Spectro-Chrome. U. S. v. 1 Device, etc. (F. D. C. No. 16892. Sample No. 16921-H.)

LIBEL FILED: On or about August 14, 1945, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 2, 1945, from Newfield, N. J., by Dinshah P. Ghadiali.

PRODUCT: 1 *Spectro-Chrome* device, together with an assortment of written, printed, and graphic matter. (The device is described in notices of judgment on drugs and devices, No. 3149.)

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in the accompanying labeling were false and misleading. (See above-referenced notice of judgment for the nature of the misbranding.)

DISPOSITION: May 17, 1950. Upon motion of the Government, the case was dismissed.

3549. Misbranding of Therm-Massage infrared heat applicator. U. S. v. 143 Cartons, etc. (F. D. C. No. 24706. Sample No. 32388-K.)

LIBEL FILED: April 8, 1948, Northern District of California.

ALLEGED SHIPMENT: On or about March 11, 1948, by Sibert & Co., from Newark, N. J.

PRODUCT: 143 cartons each containing 1 device labeled "Therm-Massage Infra-Red Heat Applicator" and a circular bearing the same name; also, in shipping cases, 39 additional copies of the above circular and copies of circulars entitled "Heat Massage Those Pains Away," "Amazing New Scientific Invention," "1st Ad, July 1st for Beauty Aid," and "Earn Extra Profits," and copies of display cards entitled "Relieve Pain Quickly" and "Therm-Massage Infra-Red." The device, together with the accompanying labeling, was at San Francisco, Calif.

Examination showed that the device consisted of two pieces of molded bakelite, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the circulars and the display cards accompanying the device contained certain statements which were false and misleading. These statements represented and suggested that the device would be effective in the cure, mitigation, and treatment of headache, sinus, muscular aches, sprains, cramps in feet or legs, stiff neck or stiff joints, colds, backache, rheumatism, aching muscles, arthritis, aching joints, neuritis, and neuralgia; that the device would be efficacious to reach down into aching muscles and joints, to bring new comfort to tortured nerves, to relax sore muscles, and to make aching nerves and joints feel better; that the device would be effective in the cure, mitigation, and treatment of foot pains, head pains, nerve pains, back pains, stiff and sore shoulders and back muscles, rheumatism, toothache, sprains and bruises, and sprained ankle; that it would cause the pain to disappear from an injured hand and enable one to get a good night's sleep; that it would be effective in the cure, mitigation, and treatment of any aches or pains; that it would relieve the stiffness in the neck muscles after a tonsillectomy; that it would relax the tiny muscles of the face, throat, and neck,

and prevent the formation of wrinkles; that it would stimulate the flow of blood into the tiny capillaries lying just under the surface and remove and eliminate the waste products accumulated in such capillaries; that it would be effective in the cure, mitigation, and treatment of sallow, muddy complexions and skim blemishes; and that it would penetrate tissues and bone, invigorate the entire system, bring fresh food to nerves and tissues, and stimulate the system to more vigorously fight disease germs. The device was not capable of fulfilling the promises of benefit stated and implied.

DISPOSITION: December 21, 1948. Ralph Clinton, San Francisco, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration. Reconditioning resulted in the destruction of all objectionable leaflets and circulars.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3542, 3544, 3545) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3550–3580

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 19, 1952.*

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3556–3559, 3561; omission of, or unsatisfactory, ingredients statements, Nos. 3556, 3558, 3560–3564; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3554, 3556, 3557, 3559–3563, 3579.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3550. Action to enjoin and restrain violations of Sections 301 (a) and 301 (k) with respect to male and female hormones. U. S. v. El-O-Pathic Pharmacy, Martin A. Clemens, and Vita Pharmacals, Inc. Tried to the court. Judgment denying application for permanent injunction reversed upon appeal. (Inj. No. 216.)

COMPLAINT FILED: September 2, 1949, Southern District of California, against the El-O-Patic Pharmacy, a corporation, Hollywood, Calif., and Martin A. Clemens, manager. On September 20, 1949, the complaint was amended to include the Vita Pharmacals, Inc., Hollywood, Calif., as a defendant, and to charge Martin A. Clemens as manager of both corporations.

VIOLATION CHARGED: The complaint alleged that the defendants were distributors of certain *male and female hormones;* that the *male hormones* consisted of *methyltestosterone tablets* (10 milligrams and 25 milligrams), *methyltestosterone in linguet form* (5 milligrams and 10 milligrams), and *methyltestosterone combined with vitamin B_1 in linguet form;* and that the *female hormones* consisted of various preparations containing *alpha-estradiol* (ranging from .01 milligram to 0.5 milligram).

The complaint alleged also that the *male and female hormones* were manufactured outside the State of California and were shipped in interstate commerce to the defendants; that during the interstate journey, the drugs bore the legend "Caution: To be dispensed only by or on the prescription of a physician"; and that the defendants repacked and relabeled the drugs and sold and distributed them without a physician's prescription.

The complaint alleged further that the defendants were violating Section 301 (k) of the Act by causing the 5 milligram and 10 milligram *methyltestosterone linguets* to become misbranded while held for sale after shipment in interstate commerce, and that they were violating Section 301 (a) of the Act by causing the introduction into interstate commerce of misbranded 5 milligram and 10 milligram *methyltestosterone linguets* and *methyltestosterone combined with vitamin B_1 in linguet form.*

The above drugs were alleged to be misbranded under Section 502 (f) (1) in that the labeling of the drugs failed to bear adequate directions for use in all conditions for which they were prescribed, recommended, and suggested in the labeling and advertising matter disseminated and sponsored by the defendants, and under Section 502 (f) (2) in that the labeling of the drugs failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form, as are necessary for the protection of the user, since the technical medical terminology in which the labeling of the drugs was couched was inadequate to warn the ordinary lay users that use of the drugs may accelerate the malignant growth of cancer of the prostate gland or may cause sterility.

It was alleged also that the 5 milligram *methyltestosterone linguets* and the *methyltestosterone with vitamin B_1 linguets* were misbranded under Section 502 (a) in that the labeling of such drugs was false and misleading since the labeling represented and suggested that the recommended daily dosage was efficacious for use in the treatment of male hormone deficiency, whereas the recommended daily dosage would be entirely ineffective for such purpose; and that the 10 milligram *methyltestosterone linguets* were misbranded under Section 502 (j) in that such linguets were dangerous to health when used in the

dosage and with the frequency prescribed, recommended, and suggested in the labeling since such use of the linquets may result in sterility and may accelerate the malignant growth of cancer of the prostate gland.

With respect to the *methyltestosterone tablets* and the *alpha-estradiol* preparations it was alleged also that the defendants would likely cause the same violations of Sections 301 (a) and 301 (k) as they were causing with respect to the 10 milligram *methyltestosterone linquets* since the defendants had sold in the past such products freely without a physician's prescription and without adequate warnings; since the *methyltestosterone tablets* had the same dangerous potentialities as the linguets; and since the unrestricted use of the *alpha-estradiol* preparations by women may accelerate the malignant growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system.

DISPOSITION: A temporary restraining order having been issued on September 2, 1949, the matter came on for hearing on the issuance of a preliminary injunction. The application for a preliminary injunction was denied on January 11, 1950, and on January 30, 1950, findings of fact and conclusions of law were filed to the effect that where the United States seeks a preliminary injunction to prevent alleged violations of the Federal Food, Drug, and Cosmetic Act, and it appears that an early trial can be had on the prayer for a permanent injunction which will substantially protect the public interest involved, a preliminary injunction should not issue.

On January 31, 1950, the case came on for trial before the court on the issue of granting a permanent injunction. For purposes of trial, the case against the Hudson Products Co., et al. (notices of judgment on drugs and devices, No. 3553) was consolidated with the instant case.

The evidence submitted at the trial of the consolidated cases consisted of a stipulated written record consisting of the pleadings and certain affidavits, together with a transcript of the criminal proceedings against the defendants in each of the consolidated cases which previously had been terminated. (See notices of judgment on drugs and devices, Nos. 2931, 2932.) The matter was taken under advisement by the court, and on May 22, 1950, after handing down findings of fact and conclusions of law, judgment was entered in each of the consolidated cases, denying the Government's application for a permanent injunction and dismissing the complaint for injunction.

An appeal was taken to the United States Court of Appeals for the Ninth Circuit, and on June 18, 1951, the following opinion was handed down by that court:

MCALLISTER, *Circuit Judge:* "This is an appeal from an order of the district court denying permanent injunctions in consolidated cases in which the government sought to restrain appellees from introducing certain allegedly misbranded drugs, known as hormones, into interstate commerce, and, further, to enjoin them from causing any acts to be done with respect to such drugs that would result in their being allegedly misbranded in (intrastate) commerce, in claimed violation of the Federal Food, Drug, and Cosmetic Act of 1938, as amended. Title 21 U. S. C. A., Sections 301 et seq.[1]

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[1] 21 U. S. C. A., Section 331, provides as follows:
"Prohibited acts—
The following acts and the causing thereof are hereby prohibited:
(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
* * *
(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the

"The government's complaint asking for injunctions in the district court thus specified two types of prohibited acts which it alleged appellees violated; and the circumstances giving rise to such complaint are as follows: It appears that the hormones in question are manufactured by pharmaceutical corporations in the eastern part of the United States and shipped to appellees in California with labeling that states, in part, 'Caution: To be dispensed only by or on the prescription of a physician.' Thereafter, the appellees relabeled the drugs to eliminate this prescription statement; and the new labeling, it was claimed, caused the drugs to become misbranded within the meaning of the statute. 21 U. S. C. A., Section 352 (a), 352 (f) (1), 352 (f) (2), 352 (j). When appellees distributed these relabeled drugs in *interstate commerce*, it was alleged that they violated that section of the statute which prohibits the introduction of misbranded drugs into interstate commerce. 21 U. S. C. A., Section 331 (a); and when they distributed such relabeled drugs in *intrastate commerce*, it was claimed that they violated that section of the statute which prohibits the doing of acts with respect to the labeling of drugs while they are held for sale after shipment, if such acts result in the drugs being misbranded, 21 U. S. C. A., Section 331 (k).

"On appeal, the government contends that the hormones, introduced into interstate commerce, distributed, and sold by appellees, were misbranded, in violation of the statute, in that they did not bear adequate directions for use; that they were dangerous to health when taken as directed; and that they did not bear adequate warnings against use in those pathological conditions where their use might be dangerous to health; all in violation of the statute. Title 21 U. S. C. A., Section 352 (a), 352 (f) (1), 352 (f) (2), 352 (j).

"The district court held that the warnings on the cartons containing the drugs were sufficient in that they stated that the hormones were for use by adult males deficient in male hormone when small dosages are prescribed or recommended by a physician for palliative relief of such symptoms; that the maintenance dosage could be extended from three to six months under supervision of a physician; that before taking the hormone, a physician should be consulted, since the hormone would not aid or relieve symptoms not associated with male hormone deficiency; and that children and young adults must not use the hormone except under constant, direct supervision of a physician. Remarking that the government wanted the drugs in question to be sold only upon the prescription of a physician, the court concluded that the question as to what effects would follow from the administration of the drugs was in dispute; that the doctors could not agree on the subject; that the government had not sustained the burden of proof; and the court, accordingly, dismissed the case.

"It is the claim of the government that it has sustained the burden of proving that the hormones in this case are inherently dangerous; that they are not safe and efficacious for use except under the supervision of a physician; that they are not suitable for self-medication, since a layman could not know when they should be used and when they should not be used; that adequate directions for unsupervised lay use can not be written; and that such drugs, if sold legally

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first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

21 U. S. C. A., Section 332, provides:

"Injunction proceedings—Jurisdiction of courts—

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, as amended, to restrain violations of section 331, except paragraphs (e), (f), (h), (i), and (j)."

21 U. S. C. A., Section 352, provides:

"Misbranded drugs and devices—

A drug shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

* * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirement.

* * *

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof."

in interstate commerce, must be dispensed only upon prescription of a physician, in accordance with the regulations of the Federal Security Administrator.[2] The government further contends that the proofs disclose that the drugs in question failed to bear adequate directions for use, in that they are offered to the public as efficacious remedies for many conditions which are not mentioned in the labeling or directions for use.

"To these contentions, appellees reply that the statute in question is not susceptible of an interpretation that the Administrator, provided for therein, is empowered to determine what drugs may be sold only on prescription; that the labeling of appellees' drugs bears adequate directions for use and warnings within the meaning of the statute; that the drugs are not dangerous to health, within the meaning of the statute; that the findings of the district court are sustained by substantial evidence; and that, since they are not clearly erroneous, they must be accepted on appeal, and the judgment affirmed. Rule 52 (a), Federal Rules of Civil Procedure.

"The evidence in the district court consisted of a stipulated written record. It comprised the pleadings, affidavits, and a transcript of proceedings in the trial of a criminal case in which appellees were found guilty by the district court, sitting without a jury, of the offense of distributing misbranded male and female sex hormone drugs. The convictions were, essentially, based upon the conclusions and findings of the district court that the hormones were dangerous to health and that the labeling claims which appellees therein made for their hormones were false and misleading. The district court stated, in the criminal case, that it was convinced beyond a reasonable doubt, that indiscriminate distribution or dispensation for use of the hormones carried not only a potential but an actual danger of injury to some persons; that the leaflets and circulars enclosed in the packages by which deliveries of sales were made, were designed to create a belief that many persons were deficient in their natural testosterone, and that, by supplementing it with the drug called by various names, a synthetic testosterone, much benefit could be derived by the user; and that the court was convinced from the evidence that these drugs did not, other than within a restricted class of cases, produce many or any of the alleviatory and beneficial effects that the labeling given them by the defendants indicated, and encouraged readers to belive they would generally produce. Appellees did not file appeals in the criminal case, but paid the fines imposed upon them.

"After the convictions in the criminal case, a different judge was assigned to try the injunction cases now before us. The evidence in these consolidated cases, here on review, consisted of the record in the prior criminal case. No additional witnesses were produced and no oral testimony was submitted. While giving due consideration to the trial court's findings, to which they are justly entitled, and with reluctance to reverse them unless well persuaded, nevertheless, under such circumstances, they do not have the weight we would otherwise be obliged to concede to them, and the scope of review is *de nova;* for this court is in as good a position as the trial court was to appraise the evidence. Equitable Life Assur. Soc. of the United States v. Irelan, 123 F. 2d 462 (C. A. 9). See Stork Restaurant, Inc. v. Sahati, et al., 166 F. 2d 348 (C. A. 9); Murphey, et al. v. United States, 179 F. 2d 743 (C. A. 9); Orvis v. Higgins, 180 F. 2d 537 (C. A. 2); Blackner, et al. v. McDermott, 176 F. 2d 498 (C. A. 10); and while, under Rule 52 (a) of the Federal Rules of Civil Procedure, findings of fact in actions tried without a jury may not be set aside unless clearly erroneous, nevertheless a finding is 'clearly erroneous' when, although there is evidence to support it, the reviewing court, on the entire evidence, is left with the definite and firm conviction that a mistake has been committed; United States v. U. S. Gypsum Co., et al., 333 U. S. 364, 394.

"For an understanding of the issues involved, an outline of the nature, use, and effect of hormones, as disclosed by the evidence, may be helpful.

"The drugs here involved are male and female sex hormones. A hormone is medically defined as a chemical substance originating in an organ, gland, or part of the body, which is conveyed through the blood to another part of the body, stimulating it to increased functional activity, and increased secretion.

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[2] Title 21, Code of Federal Regulations, Sections 1, et seq. (1949 Ed.).

"The principal drug in question is testosterone, which is a male sex hormone. This hormone is generated by the reproductive organs of the normal adult male. Male sex hormones are also known as androgens, and female sex hormones, as estrogens. They are not only generated in the reproductive organs; the hormones, in this case, are prepared from extracts of animal tissues and fluids, as well as made synthetically by complex chemical fusions that have the qualities of natural hormones.

"Leaders of the medical profession in America, practitioners, professors of medicine, as well as research scholars, scientific men of conservative attitude, appearing as witnesses for the government in this case, referred to the 'dramatic results' produced by testosterone, and described the effects of its use as 'spectacular,' 'amazing,' 'astounding,' and 'absolutely wonderful.' But as government counsel observe, the drug is capable of dramatic good and, at the same time is capable of dramatic evil.

"The good and evil effects of the administration of testosterone are more readily appreciated when it is understood how the body naturally produces and utilizes this hormone. The natural generation of testosterone in the reproductive organs of the normal adult male is governed by a delicate endocrine, or glandular balance, that exists between such organs and the pituitary gland, the small gland located at the base of the brain, of which one function is the production of hormones known as gonadotrophins. These gonadotrophins stimulate the testes to produce spermatozoa and testosterone. Testosterone is responsible for the changes which characterize a boy's development through puberty to manhood. It causes an unfolding of the secondary sex characteristics such as growth of sex organs, muscles, enlargement of the larynx with consequent change of voice, and like developments.

"In the normal functioning of the pituitary and testicular glands, there is an interplay between the testicular hormone, testosterone and the pituitary hormones, gonadotrophins. If the production of the pituitary hormone decreases, the testes are no longer properly stimulated, and, as a result, they produce a lesser amount of testosterone and spermatozoa. The lowered body level of testosterone, in turn, stimulates the pituitary gland into greater activity. As described by one of the medical experts, its action is like a thermostat, as, when the heat drops, the thermometer records it and turns the furnace on. As the testosterone level drops, the pituitary gland is turned on to produce more gonadotrophins. However, if the level of the testosterone gets too high, then the activity of the pituitary gland is lessened, just as when the temperature gets too high, the furnace is turned off.

"With respect to the effect of the administration of sex hormones on human beings, the government's case rested on the testimony of witnesses who, from the evidence, appear to be among the foremost medical authorities in this country on the subject, comprising research specialists in hormones, heads of urology departments in great hospitals, professors of urology, research urologists, professors of pharmacology and toxicology, professors of surgery, specialists in the study and treatment of cancer, professors of anatomy, and endocrinologists, as well as medical practitioners in these various fields of medicine.

"Among these witnesses was Dr. Charles Huggins, Professor of Urology and head of that department in the hospital of the University of Chicago, whose work, for twelve years prior to the trial was devoted almost exclusively to the male hormone, and its action in normal and cancerous individuals, and who, from the evidence, is apparently the chief authority on the effects of testosterone. According to Dr. Huggins, the administration of this drug results in startling changes in men, known as hypogonads, and in castrates. Describing a hypogonad as a man in whom the male sex hormone is produced in small amounts or not at all, Dr. Huggins testified that it is usually—not always—a congenital state in which the reproductive organs and secondary sex characteristics remain undeveloped; the male speaks with a soprano voice; he has no growth of hair on the face or the body; and is completely unable to have any sex relationship. By administering male hormones to such a person, his sexual 'drive' is restored, as well as the normal male sex characteristics. Impotence is replaced by potency. 'In hypogonadism, it had spectacular effects.' If testosterone is administered to castrates, most of whom have suffered such impairment as a result of the explosion of land mines during the war, it will develop or restore their sex drive and secondary sex characteristics, and make such persons practically normal males. Among

methods to ascertain whether a person suffers from hormone deficiency, are clinical observations and complex laboratory tests.

"Dr. Norris J. Heckel, Professor of Urology at the College of Medicine of the University of Illinois, and Chairman of the Department of Urology at the Presbyterian Hospital in Chicago, a leading medical authority on this subject, testified that when, by the action of testosterone, 'you can take a female male and make that individual into a man and establish him back into his community and make him a perfectly normal male, it is really amazing and astounding.'

"The administration of testosterone is, however, accompanied by grave dangers to the health, and, often, to the life of the person to whom it is administered. Dr. Huggins testified that the administration of testosterone to a child would result in tremendous growth of the sex organs and bring about the secondary sex characteristics of change and depth of the voice and growth of hair on the face and chest; that to give the drug to a child of five or ten years of age would result in a tremendous sex drive; that it would render a child sexually mature at the age of two years with the exception that sperms would not be produced.

"According to the evidence of the government medical expert witnesses, it appears that, from experimental research studies conducted by them, the administration of testosterone inhibits or reduces the activity of the pituitary gland in the production of gonadotrophins, and this, in turn, results in a decrease in the activity of the testes, both in the production of spermatozoa and in the production of testosterone. As a consequence, the administration of testosterone, by upsetting the hormonal balance of the body, tends to produce a condition of infertility or sterility that may continue for months or years, depending upon the amount and duration of administration, and the condition of the reproductive organs. Moreover, on the basis of research, it appears that men, from the age of forty to sixty, are more likely to be susceptible to the damaging effects of testosterone than younger men.

"The great dangers, however, encountered in the administration of testosterone appear, from the evidence, to be concerned with the activation and acceleration of unperceived, dormant, or inactive cancer growths in the human body. A man may have cancer of the prostate gland and not be aware of it, for there are no symptoms through which a person may diagnose his own case; but this type of cancer is the cause of death of 5 per cent of men over fifty years of age . From post-mortem examinations, it appears that between one-sixth and one-third of men over fifty years of age have dormant lilliputian cancers of their prostate glands. Diagnosable cancer of the prostate ranges from one out of thirty-five men aged fifty who consult with a urologist with regard to difficulty in urinating, to one out of twelve aged sixty, with the same difficulty. Prostatic cancer is usually diagnosed by a physician by rectal examination, with palpation of the prostate gland; and various laboratory tests, including biopsy, or microscopic examination of small samples of testicular tissue removed by surgical operation, are also available. Early prostate cancer is successfully treated by the removal of the entire prostate gland.

"The remarkable relationship of cancer to testosterone is perceived when testosterone is administered to a man who has a dormant or inactive cancer of the prostate gland. The drug will activate such cancers and greatly accelerate its growth, causing it to metastasize, or spread, to other parts of the body, eventually becoming impossible to control; and even testosterone produced naturally by the body tends to activate such dormant cancers. However, although dormant or active cancer of the prostate gland occurs most frequently in middle-aged or older men, nature itself provides a mechanism whereby the body's production of testosterone is reduced as much as 50% in those age groups. Consequently, while a large number of men over fifty years of age have dormant cancerous cells in their prostate glands, the lowered natural supply of testosterone usually permits those cells to remain dormant and harmless. Yet they can be activated and stimulated into malignant cancers by the artificial administration of testosterone.

"Where cancer has spread beyond the confines of the prostate gland, treatment calls for the elimination of testosterone from the body as far as possible. This is sometimes accomplished by surgical castration, which removes the major source of the body's supply of testosterone. It has been found that

while the administration of testosterone has made prostatic cancers flourish, the removal of testosterone causes such cancers to wither, shrink, and disappear.

"During the last ten or twelve years, another remarkable discovery has been made in this medical field. It has been found that the administration to a man suffering from cancer, of estrogenic drugs, or female hormones, causes the cancer to decrease. Even where the cancer has spread to a man's chest, which has been riddled with metastatic lesions, the administration of female hormones—which are antagonistic to male hormones and neutralize them—has caused such lesions to shrivel up in an amazing way, and disappear. While it appears that the administration of female hormones to a man suffering from cancer may cause such cancer to dry up and disappear, the administration of female hormones to a woman suffering from cancer—before her change of life—accelerates its growth; and, it is to be remarked, many women who have, for instance, cancer of the breast, are not aware of that fact without medical observation and diagnosis. Female hormones accelerate malignant growth not only of cancer of the breast, but of the uterus, to the point where its control becomes impossible. Yet when male hormones have been administered to women suffering from such cancers, they have decreased.[3]

"High potency female sex hormones, which are administered orally, by injection, or by rubbing on the skin, are useful in breast development in limited cases of young women, usually under twenty, who manifest hormone deficiency, in terms of ovarian function, with the result that the breast and genital tracts are undeveloped; but there is no direct relationship between female sex deficiency and small breasts. A woman may have small breasts, yet not suffer from a hormone deficiency; and if she does not suffer from such deficiency, the use of hormones will be of no value in causing breast enlargement. There are no subjective symptoms by which a woman can correctly diagnose herself as having a female sex hormone deficiency.

"According to the evidence of the government's expert medical witnesses, the administration of testosterone is contra-indicated, or medically forbidden, in all cases where cancer is suspected in men, and, likewise, female hormones, in the presence of cancer in women, at or past the menopause, although in older women, with seeming incongruity, they sometimes inhibit such growths.

"Male hormones, aside from their use in treating cancers in women, are properly prescribed, according to the government medical witnesses, with some minor exceptions,[4] when there is no suspicion of cancer,[5] and only in the rare

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[3] It is interesting to note that for the first time in medical history, cancer of the thyroid gland in the neck has responded to treatment with male hormone, in the case of a woman who had been ill with such cancer for nine years, and who, since the hormone treatment, left her bed, and has since been leading a normal life for the past eight months, according to the report of Dr. Henry M. Lemon, of Boston University, to the American Cancer Society. "The patient's bones still are shot through with cancer," Dr. Lemon stated. "There is no telling whether any of this can be cleared up and, if so, how long the remission will last." Large doses of X-ray had previously been tried without success. The cancer did not pick up radio-active iodine, as some thyroid cancers do, so that treatment offered no hope. Scientific interest in this case, Dr. Lemon pointed out, centers on the opportunity to study just what effect the male hormone has on protein synthesis in thyroid cancer. Science News Letter, March 31, 1951.

[4] It has been found that testosterone produces good results in causing growth of epithelium where the kidneys are damaged by nephritis; that it has been noticed that the drug brings about re-growth of tissue, in the healing of indolent ulcers of the lower leg that have failed to heal by the use of any other method; and that, in cases where elderly men wake up in the night, become disoriented and mentally disturbed, testosterone is sometimes used with good effect to remedy such a condition.

[5] At the Annual Meeting of the American Medical Association, held on June 12, 1951, Dr. Huggins is stated to have reported additional discoveries with reference to the relationship between hormones and cancer, according to a signed article by William L. Laurence, noted science news reporter of the New York Times. The report, according to Mr. Laurence, announced that two human patients who were near death from a recurrence of cancer of the prostate gland, "have gained a new lease on life" after total removal of both their adrenal glands. "The removal of both adrenal glands, ordinarily essential to the maintenance of life, has been made possible by the availability of cortisone, one of the vital life-giving hormones secreted by the outer layer of the glands, which are located astride the kidneys.

"The new surgical procedure, a major development in the art of surgery, was described before a large audience of distinguished physicians and surgeons from all parts of the country by Prof. Charles B. Huggins and Assistant Prof. D. M. Bergenstal of the School of Medicine, University of Chicago.

"Professor Huggins gained international renown about twelve years ago when he discovered that prostate cancer thrives on the male hormones and that castration, which eliminates the secretion of male hormones, shrinks and checks its further growth. As a

instances where the patient is suffering from a male hormone deficiency—that is, where he is a castrate, or a hypogonad; and only between one to two men out of a thousand who are admitted for hospital treatment are hypogonads. Dr. Huggins testified that only about thirty men in the last eleven years have been treated, at his hospital, for male hormone deficiency. Female hormones, aside from their use in treating cancers in men, are properly prescribed only where there is no suspicion of cancer and where the patient is suffering from the effects of a female hormone deficiency.

"Among the witnesses for the government was Dr. Elmer Belt, urologist, associated with research work in the Belt Urological Group, and a member of the California State Board of Health, who had observed more than 1,000 cases of prostate cancer in men; Dr. Ian Macdonald, Associate Professor of Surgery at the University of Southern California School of Medicine, who had treated more than 1,000 cancers in women; as well as others who are among the pioneers and most experienced leaders in the field of hormone research, and in the use of such drugs in cases of hormone deficiency and cancer. In addition to the evidence above outlined to the effect that sex hormones are dangerous and highly potent, but drugs which are useful in certain cases, it appeared, according to the government witnesses, that the consensus of informed and expert opinion was that the dosages of testosterone suggested by appellees' labeling of the drugs would accelerate the growth of a dormant or active cancer of the prostate gland; that no lay person was capable of judging whether he should use such drugs; that they might result in the greatest danger to his health and life; that the judgment as to who should receive and who should not receive the drugs was a matter for doctors alone and a consideration of the highest importance to the patient; that the drug should always be administered under the supervision of someone with knowledge of the matter; that to use the hormones required the most meticulous diagnosis and supervision, and that it is necessary to maintain such supervision over the patient during the course of the treatment, controlled by frequent examinations; and that, as one of the government experts said, in referring to the drug, 'The amount of potential harm it has is much greater than the good it can do, if used unbridled.'

"Appellees introduced as expert testimony with reference to the use of the drug, the evidence of three practicing physicians. However, none of these witnesses was a urologist, research expert, or cancer specialist, and none had ever conducted any clinical, laboratory, or scientific tests with regard to hormones or cancer. One of the witnesses, during his ten years of general practice, had seen cancer of the prostate gland about once a year; and although he gave thousands of physical examinations during the war, he stated that he found no such cancers except on very rare occasions. When a patient calls upon him complaining of unusual weakness, loss of memory, inability to concentrate, nervousness, or general fatigue, or a combination of these complaints, he talks with him a few moments to try to determine if there is anything else that bothers him, such as a bad heart; and if he can determine that the patient has no organic, pathological condition, he prescribes or injects male hormones.

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result, many thousands of human beings, who otherwise would have been doomed to certain death, are still alive, many of them as long as twelve years after operation.

"Castration is accomplished either by surgery or by the administration of female hormones that neutralize the male hormones.

"Unfortunately many of the prostate cancers recur after either surgical or chemical castration, and in such cases there has been until now nothing that medicine or surgery could offer to these victims. The reason for such recurrences is that the adrenal glands also secrete large quantities of male hormones, and that after castration by either method they are stimulated to increase their output.

"However, there was nothing that could be done for these unfortunates since it was impossible to remove the adrenal glands because the adrenal hormone cortin is vital for the maintenance of life. The availability of cortisone, which is widely used in the relief of the symptoms of rheumatoid arthritis, rheumatic fever and many other major chronic ills, has at last opened the way for adding further years to the lives of prostate cancer victims.

"As little as twenty-five to fifty milligrams of cortisone taken daily by mouth, Professor Huggins reported, has maintained the patients whose adrenals have been removed, in good health three and four months, respectively, after operation. Both of them have gone back to work.

"While the new surgical procedure is still in its exploratory stages, it offers new hope for thousands of victims of prostate cancer, of whom more than 2,000 die every year. It also opens a new surgical approach to high blood pressure, in which the adrenal glands appear to be somehow involved, and lends further support to the hypothesis that cancer in general is the result of an imbalance in glandular secretions." New York Times, June 13, 1951.

He takes no tests of the patient, and prescribes testosterone to patients on an average of about once a day. He further stated that he has never encountered what he considers adverse results but has occasionally had good results, many of his patients being relieved of the symptoms above mentioned. He further stated that his reading on the subject suggested that testosterone aggravates or might possibly aggravate cancer of the prostate, but that the literature on the subject is not uniform, there being much confusion. He himself has no opinion on the subject. Many doctors do not know, and he stated that he is one of them. He doubts that the administration of the drug produces sterility. However, he does not believe he would prescribe the drug to a man who wished to procreate, or to a patient in whom he found any suggestion of cancer of the prostate.

"Another of appellees' medical witnesses testified that he frequently prescribed the drug. If a man in middle life comes to him and complains of nervousness, flushes, sweats, chills, general weakness, lack of physical strength, impaired memory, inability to concentrate on activities, and a tendency to evade them, he takes a general history of the person and his past illnesses, and after a complete physical examination, if he finds no evidence of a disease of a specific nature, he prescribes or administers testosterone. He has done this on many occasions and found, as a result, the patient's symptoms appeared relieved. He stated that on no such occasion has he ever encountered adverse results. He associates the 'male climacteric' with a diminution of the secretion of the interstitial cells of the testes. He prescribes the drug about once a week. In his practice of thirty years, he has seen three cases of cancer of the prostate. If a patient evinces some suspicion of prostatic cancer, he refers him to a urologist. He would, however, prescribe female hormones to a woman suffering from cancer if he thought she needed it; and he stated he would also prescribe testosterone to a man with cancer of the prostate if, in his opinion, he needed it, his determination in such a case depending on whether the patient had the 'middle-aged symptoms.' While he considered one of the government experts on the subject an eminent physician in his field, he declared that he would 'never accept any medical man as an authority anywhere.'

"The third medical witness for appellees was a physician of high scholastic attainments during his college work, who had been attached to the Veterans' Administration for two years after the completion of his medical studies, and had been in general practice one year at the time of his testimony. He associates the 'male climacteric' with a hormone deficiency, the symptoms being a loss of libido, or sexual drive, loss of a sense of well-being, nervousness, irritability, and sleeplessness. When men of middle age complain of these symptoms, he prescribes testosterone, and the patient thereafter often appears definitely relieved. He tries the drug out on such patients, and if it helps them, concludes that they suffer from a hormone deficiency. Prior to prescribing the drug, he gives a general physical examination, but does not give the various tests mentioned by the government medical witnesses, as the general practitioner does not have the equipment to do so, and the patient doesn't have the funds to pay for such tests. He stated that he had read the literature relating to testosterone and its relationship to cancer of the prostate, but that the articles are pro and contra. Based on what he has read and on his experience, he firmly believes that testosterone is not dangerous. It may be, incidentally, said that the opinion of the government expert witnesses in this field is that a condition, described by appellees' witnesses, as the 'male climacteric,' or a male change of life, does not exist, although some of the government's witnesses referred to a certain 'unusual and rarely encountered condition' of hormonal deficiency, as a male climacteric. But, according to the government's witnesses, there is no relation between middle age and a condition of hormone deficiency.

"Much of the testimony of appellees' medical witnesses—in fact, the whole force of the testimony of two of the three witnesses, who are of the opinion that testosterone has no effect upon male fertility, and who see no danger in its administration to patients suffering from cancer—makes most incongruous appellees' insistent claims in this case that the labels attached to the drugs they distribute adequately warn against the danger of using the drug by anyone who suffers from cancer of the prostate, and caution against its use

for the reason that it may result in infertility.[6] Moreover, the same testimony of appellees' medical witnesses was considered in the criminal cases, and was there rejected by the court which found that the drugs were dangerous; that appellees had made representations designed to create a belief that most persons were deficient in their natural testosterone, and that by supplementing it with synthetic testosterone, much benefit would be derived; and finally, that the court was convinced that such drugs, other than within a restricted class of cases, did not produce any of the alleviatory and beneficial effects that the label given them by appellees indicated and encouraged prospective buyers to believe they would produce. Having been convicted in those cases, having paid their fines without appeal, and having purportedly attempted to remedy the labeling complained of in order to comply with the law as there adjudicated, it may be supposed that appellees accepted the court's findings in the criminal cases as valid. If such findings were valid, accepted, and unchallenged in the criminal cases, they would seem equally valid in the instant case in so far as here applicable, since they would rest upon the same proofs and evidence in both cases. In fact, a puzzling aspect of the arguments of appellees in this case is that they are not, in this instance, challenging the dangerous potentiality of the hormones. Having accepted their conviction in the criminal cases as valid, they here contend that the changes in their labeling have brought their drugs into full compliance with the law.

"With reference to appellees' arguments that the credibility of two of the important government medical witnesses had been conclusively impeached, it appears that one of the appellees, and others employed by them, called on the physicians in question, requesting a prescription of testosterone. In one of the cases, it was represented that appellee's doctor, in another state, whose name he gave, had prescribed the drug regularly; that his doctor had told him to call upon the witness in case of need; and that, at the time, he required a further supply of the drug in order to continue the prescribed treatment. In another case, a prescription label on a bottle was shown to the doctor, indicating that the drug had been prescribed by a physician in another state, and the witness was asked to prescribe the drug in order to continue the treatment, which, it was represented, had been theretofore beneficial. Another instance was similar to the foregoing. We are not impressed with these contentions that, because the drug was prescribed by the government witnesses under such circumstances, the credibility of the witnesses was impeached in any important particular.

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[6] Typical label:

(Front Panel)

"VITA HORMONES 100 Tablets

Each Tablet Contains 10 Mg Methyl Testosterone.

SUGGESTED DOSAGE: One tablet upon arising before breakfast or one tablet shortly before retiring. Tablets should be held between gum and cheek, or under tongue, and allowed to dissolve slowly, so that hormone is absorbed by mouth tissues (saliva may be swallowed while tablet is in mouth, but do not swallow tablet). The maintenance dosage can be extended from three to six months, under supervision of a physician.

DIRECTIONS: For use by adult males deficient in male hormone when small dosages of male hormone are prescribed or recommended by a physician for palliative relief of such symptoms.

Distributed by VITA PHARMACALS, INC.

1109½ No. Western Ave. Hollywood 27, Calif.

HOllywood 9–1722

(Read Side Panels)

(Side Panel)

"It is impossible for a layman to determine whether he has a male hormone deficiency, as similar symptoms may be caused by other conditions. Therefore, before taking testosterone a physician should be consulted, since testosterone will not aid or relieve symptoms not associated with male hormone deficiency. Children and young adults must not use except under constant direct supervision of a physician.

(Side Panel)

"CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardiovascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed."

"In this controversy, it is, of course, not to be supposed that this court assumes to act as an arbiter between conflicting medical opinions or schools of scientific thought. We have to determine the case solely on the evidence before us and the law. From the evidence before us, we are of the opinion that, while there is some difference of view, the expert testimony of the government's medical witnesses in this case is entitled to far greater weight than the testimony of other witnesses. We are not bound to reject informed medical judgment every time medical witnesses can be produced who blindly adhere to a curative technique discredited by reliable scientific experiences. See Reilly v. Pinkus, 338 U. S. 269. The testimony of the government's witnesses here appears to us completely credible and persuasive, and we accept it, in so far as this case is concerned, as proof of the facts in controversy. From such evidence, we are of the opinion that the drugs in question are inherently dangerous; that they are not safe and efficacious for use except under the supervision of a physician; and that they are not suitable for self-medication, since a layman can not know when they should be used and when they should not be used. Moreover, it is to be remarked that appellees' labels themselves, set forth that it is impossible for a layman to determine whether he has a male hormone deficiency; that before taking testosterone, a physician should be consulted; that children or young adults must not use the drug except under constant direct supervision of a physician; that it should not be taken by anyone with cancer of the prostate, or defects of spermatogenesis; and that it is for use by adult males deficient in male hormone, when small dosages are prescribed or recommended by a physician. These labels themselves clearly demonstrate that adequate directions for unsupervised use can not be written; and the testimony of the government's medical witnesses, which we accept, only strikingly emphasizes this important and crucial fact. Obviously, in such cases, the direction on the label that 'a physician should be consulted,' and the directions that the drug be used when dosages are prescribed or recommended by a physician, are not enough to constitute 'adequate directions for use' within the meaning of the statute.

"Since the drugs in question are inherently dangerous and not safe and efficacious for use except under the supervision of a physician, in view of the fact that a layman would not know when and when not to use them, and since adequate directions for unsupervised lay use can not be written, such drugs, if sold legally in interstate channels, can only be dispensed if the label bears, in accordance with the statute, 'adequate directions for use,' in the light of the given circumstances. The only adequate instructions for use in such cases would seem to be a caution that it be used only on the prescription of a physician. Would such a caution or such a direction constitute 'adequate directions for use' within the meaning of the statute? The inscription on a label, 'Caution—To be used only by or on the prescription of a physician,' would appear to constitute what is comprised within 'adequate directions for use' acording to the intendment of the law. United States v. Sullivan, 332 U. S. 689, 691. It is to be, of course, observed that the Supreme Court, in the above case, remarked that such an inscription appeared to constitute adequate directions, *since it was required by the regulation issued by the Administrator pursuant to authority of the Act.* And in this regard, we are mindful of the strenuous argument addressed to the court by counsel for appellee to the effect that the only power which the statute confers upon the Administrator to issue regulations in such cases, is authority to issue regulations exempting drugs from the requirement of 'adequate directions for use,' when that requirement is not 'necessary to the protection of the public health'; and that, accordingly, the statute gives the Administrator no power to issue regulations providing that drugs be sold only on the prescription of a physician.

"Necessarily, therefore, counsel for appellees finds his argument in conflict with the above statement of the Supreme Court in the *Sullivan* case, since he contends that when the Administrator exempts a drug from such directions, he has no authority to do anything more, such as, in this case, requiring, by regulation, compliance with other conditions and safeguards which, in his discretion, seem proper and necessary for the protection of the public health. The statute, however, does not state the exemption. It authorizes the formulation of the exemption by regulations. See Arner Co. v. United States, 142 F. 2d 730, 736 (C. A. 1). The statute provides that, if the requirement of

adequate directions is not necessary to the public health, the Administrator is empowered to promulgate regulations exempting the drug from such requirement. The government takes the stand that the Administrator may exempt the drug from the requirement of adequate directions for use, as not necessary to the public health, *provided* that there be compliance with the regulation requiring the label to state that the drug be used only on the prescription of a physician. Unless contrary to law, arbitrary, or unreasonable, the terms of exemption from adequate directions for use can be prescribed, in the discretion of the Administrator. Arner Co. v. United States, supra.

"May the Act be construed to authorize such exemption, conditioned upon compliance with the requirement that the drug be used only on the prescription of a physician? The statute is remedial and should be liberally construed so as to carry out its beneficent purposes, Research Laboratories v. United States, 167 F. 2d 410 (C. C. A. 9); and its construction should be infused by regard for such purposes, touching phases of the lives and health of people which are largely beyond self-protection, Arner Co. v. United States, supra. The Act as a whole was designed primarily to protect consumers from dangerous products, United States v. Sullivan, supra; its purpose is to protect the public, the vast multitude which includes the ignorant, the unthinking, and the credulous who, when making a purchase, do not stop to analyze. United States v. 62 Packages of Marmola Prescription Tablets, 48 F. Supp. 878, Aff. 142 F. 2d 107 (C. A. 7). See also Pasadena Research Laboratories v. United States, 169 F. 2d 375 (C. A. 9).

"A liberal interpretation of the Act, having in mind its background and purposes, requires us to sustain the action of the Administrator on the ground that he was empowered, under the statute, to exempt by regulation the drugs in question from the requirement that the label bear adequate instructions for use, conditioned upon its bearing an inscription that it be used only on the prescription of a physician. Under such construction, the regulation is not contrary to law, arbitrary, or unreasonable. This is not the same as conferring upon the Administrator a general authority to create classes of drugs or to specify the manner in which drugs of each class are sold, as argued by appellees; but where no adequate directions for use of specified dangerous drugs can be written for purposes of self-medication by a layman, and they can be safely taken only upon the advice and under the supervision of a physician, it is within the statutory power conferred upon the Administrator to require, by regulation, that the label set forth that they be taken only upon prescription of a physician. From another viewpoint, it would seem, from the evidence, that, aside from the regulation, the only adequate direction for use of the drug in question would be a requirement that it be taken only on the prescription of a physician and that, in default of a label embodying such direction, the drug would be misbranded under the statute. 21 U. S. C. A., Section 352 (f) (1). It is our conclusion and judgment that appellees' drugs did not bear adequate directions for use, and must, therefore, be deemed to be misbranded.

"Were it necessary to decide this case on certain additional grounds relied on by the government, we would find ourselves in agreement with its conclusions therein. The government contends that, from another aspect, the labeling of appellees' drugs fails to bear adequate directions for use, because it does not state the ailments of the body for which the drug is, through any means, held out to the public as an efficacious remedy. The evidence discloses that prior to the trial of the criminal cases, appellees' labeling and circulars stated that 'lack of sexual power' and 'lack of sexual desire' were remedied by testosterone; that it restored 'sexual desire and ability to fulfil it'; and that 'the male hormone discloses magic far beyond the merely sexual.' Shortly after the criminal convictions on July 13, 1949, appellees advertised in newspapers: 'Sensational New Formula! Male Hormones. Testosterone now combined with Vitamin B at a new low price. Mailed to you in plain wrapper. Send check, cash or money order. CAUTION! Take only as directed. DOUBLE YOUR MONEY BACK GUARANTEE. If, after taking these tablets for at least 10 days, you don't feel that you are deriving benefit from their use, return box and the unused tablets and we will cheerfully give you DOUBLE your money back.' Another newspaper advertisement set forth: 'Men Over 40. The New Hormone Tablets. Testosterone

Propionate. Full potency' with a guarantee of money refunded if the purchaser was not benefited within ten days. In addition, shortly after the criminal convictions, appellees sent out circulars to druggists stating: 'Dear Sir: Everybody's talking about hormones . . . hormones mean big volume and new profits to all druggists . . . hormones are the hottest thing in pharmaceuticals today . . . they'll soon be bigger than vitamins everywhere. There's been a flood of publicity, a best-selling book, dozens of national magazine articles, countless newspaper stories.' One circular sent to individuals through the mail gave a bargain price list of male hormones in lots up to 1,000 tablets, regular strength, and 500 tablets, double strength, with the statement: 'Take only as directed.' One of the circulars to druggists announced:

> Thousands of men and women everywhere are interested in hormones—need hormones—want hormones. They'll buy them wherever they can get them.
>
> Most people don't know where to get them!
>
> That's why Hudson Products Co., Inc., is launching an intensive national advertising campaign, telling every man and woman they can buy Hudson Hormones at their favorite drugstore. Twenty-five million match books will be circulated in California alone.

Moreover, it appears that almost immediately after the criminal convictions, appellees bought up extensive lists of persons who had previously purchased male hormones when they were sold under the widespread advertising and representations condemned, in effect, in the criminal cases, in order to circularize such persons and keep them as customers.

"It is difficult to discern any legitimate purpose in an intensive advertising campaign to tell every man and every woman that they can buy these dangerous drugs at their favorite drugstore, if they are to be taken only in consultation with a physician and when prescribed or recommended by him. In the light of these circulars and advertisements, it is impossible to conclude that the drugs were being sold for the limited purpose, set forth in the directions for use—to be taken, as the label stated, after consultation with a physician; and for use by adult males deficient in sex hormones, 'when small dosages of male hormone are prescribed or recommended by a physician' for palliative relief of such symptoms.

"The district court, in the criminal cases, had found that the indiscriminate distribution or dispensation of testosterone carried not only a potential but an actual danger of injury, and that, outside a restricted class of cases, the drugs produced none of the benefits which appellees encouraged the readers to believe they would produce. If appellees accept this finding, as they claim they do, then, for what purpose are they now distributing this dangerous drug in such an indiscriminate way and in such huge quantities? It is plain they are selling it for uses other than set forth in the directions in the labels. Twenty-five million match cover advertisements for distribution in California alone is hardly assurance that appellees are limiting the sales of these dangerous drugs to such restricted legitimate use as was mentioned by the district court in its findings in the criminal cases, or established by the evidence in this case. It is impossible to reconcile appellees' claimed acceptance of the court's conclusions in the criminal cases and their contention that they have since brought their labeling in full compliance with the law therein set forth, with their conduct since that time. The conclusion is inescapable that appellees are capitalizing on their previous representations and advertisements, and that the drugs are still being sold indiscriminately for 'overcoming impotence,' 'lack of sexual power,' and the like, that brought about their convictions in the criminal cases, although this is largely implicit rather than explicit in their labeling, advertising, and mail order business. Yet, this was not wholly implicit, for circulars distributed with other circulars relating to hormones at bargain prices, advertising a drug for certain sexual purposes; statements in circulars distributed in mail order letters that 'we don't want this great discovery (testosterone) to be the subject of snickers or back-room talk,' and the advice that the drugs would be mailed to customers in plain paper, indicate that the circulars were to be read in the light of the prospective customers' sexual problems and that the customers

themselves, rather than physicians, could judge of the beneficial results within ten days of taking. All of the foregoing is to be considered in the light of appellees' extensive campaign of advertising to tell *every man* and *every woman* where they could buy the hormones at their favorite drugstores.

"'The words, "adequate directions for use," necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling * * *.' United States v. Various Quantities of 'Instant Alberty Food,' 83 F. Supp. 882 (D. C. D. C.); see Alberty Food Products Co. v. United States, 185 F. 2d 321 (C. A. 9); Colgrove, et al. v. United States, 176 F. 2d 614 (C. A. 9). The proofs are convincing that appellees are implicitly holding out to the public, and selling, the drugs in question for some use other than that set forth in the directions for use.

"Moreover, the evidence discloses that in an investigation conducted in California, where the drugs were sold by appellees, by the Food and Drug Administration, subsequent to the criminal convictions, out of nineteen purchasers of the drug in question, selected at random, only one was deterred from taking testosterone as a result of reading the label. Another purchaser happened to read a newspaper article warning of the dangers and decided not to use it; and a third purchaser considered that its use was causing tension around his heart and nervousness, and stopped taking it. The remaining sixteen took the drug without consulting a physician. This evidence rather clearly shows that there were not adequate directions for use, or adequate warnings to the public. For the label[7] would not necessarily indicate to a prospective user anything more than that the purpose of consulting a physician was to determine whether the drug would be beneficial to him; and there is no indication in the warning label that a physician should be consulted to determine whether the drug was dangerous for him. The evidence disclosed that the reference to a physician in the labeling of the drug had little effect upon the public, and indicates how unlikely it was that a mail order, or 'over the counter,' purchaser of this dangerous drug would take it to a physician and ask whether he should use it.

"In the submission of their arguments, appellees leave the crucial questions in the case unanswered. If it is dangerous to take a drug except under a physician's supervision, and if the distributors of such a drug do not want persons to take it except under a physician's supervision, what objection can they have to selling it only upon the prescription of a physician? And if they do not want persons to take it except under a physician's supervision, why do they exploit and promote such a drug, so restricted in its usefulness, by indiscriminate, widespread appeal directly to the public, offering customers sales in bargain lots when, as a result of such methods, it is most unlikely that physicians will be consulted by such customers? The failure and inability to give any adequate answers to these questions have transcendent significance. For the reasons we have indicated, in addition to those heretofore discussed, it is our conclusion that appellees' drugs did not bear adequate directions for use; that, further, they did not bear the adequate warnings required by the statute; and that such drugs must, therefore, be deemed to be misbranded.

"While appellees were not distributing female hormones when the complaints were filed in these cases, they had previously been engaged in such merchandising transactions. Circulars issued by appellee, Hudson Products Co., since the criminal cases, indicated a likelihood that they would do so again; and, although not a part of the record, the government, in its brief, set forth that newspaper advertisements by appellee, Vita Pharmacals, Inc., of female hormones had appeared since the filing of the complaints in the instant cases; and the facts so alleged are not denied. The government, in its complaints, asked for injunctions against the distribution of the female hormones in question. Under the above circumstances, we are of the view that such injunctions may properly issue.

"In consideration of the foregoing, the judgment of the district court is

[7] See footnote 6.

reversed, and the case remanded, with directions to issue permanent injunctions as prayed for by the government in its complaints."

On June 26, 1951, the Government filed a motion with the United States Court of Appeals for the Ninth Circuit for issuance of its mandate in the cases to the District Court, with instructions to issue temporary restraining orders without notice pending the issuance of a permanent injunction. A motion was filed also on behalf of the defendants, requesting a stay of the mandate. The following opinion was handed down by the appellate court in denial of both motions:

FOR THE COURT: "The United States has moved this court for an order directing that mandate be issued forthwith. The motion is based upon the court's finding in its opinion of June 18, 1951, 'that the drugs in question are inherently dangerous; that they are not safe and efficacious for use except under the supervision of a physician; and that they are not suitable for self-medication, since a layman cannot know when they should be used and when they should not be used.'

"In support of the motion, the United States has produced two circulars mailed by the appellee Vita Pharmacals, one dated May, 1951, and the other circulated after this court's decision. The first circular advises of the pendency of the appeal in this court of this case and of the possibility of an adverse decision in which event appellee will be forced to discontinue the sale of its hormone products immediately. The circular therefore suggests that the recipient order an ample supply as an appeal to the United States Supreme Court would take at least a year to be heard. The exhortation is 'Don't delay. Order today . . As this may be your last opportunity to buy our products.' The second circular is headed in large type: 'QUITTING BUSINESS—IMPORTANT NOTICE! LAST TWO WEEKS TO PURCHASE OUR VITA HORMONE PRODUCTS.' The circular announces the decision of this court and suggests that in view of the impending cessation of the sales, the recipient stock up with an ample supply. There is no showing as to the extent to which such communications had been circulated, but the first circular recites: 'This is an answer to thousands of letters we have received from our interested customers with reference to the outcome of our FEDERAL LITIGATION.'

"The Government's motion proceeds upon the theory that until this court's mandate is returned to the District Court that court is without power to issue an injunction, and that unless the issuance of the mandate be expedited, the appellees will flood the country with products which this court has now determined to be highly dangerous to the public under the conditions which attended their distribution heretofore.

"We are of the opinion that upon the showing made by the United States, it is entitled to immediate relief by way of a temporary injunction which, as this court's opinion discloses, is required in the interest of the protection of the public. We think that the wording of the circulars mentioned would be well calculated to induce the appellees' customers to stock up with supplies of these drugs not merely for a few months but for years to come in view of the customers' reasonable apprehension that this court's judgment might ultimately be affirmed and that there might not be another opportunity to buy so freely. However, we do not find it desirable that the mandate issue forthwith in view of the fact that the time for filing petition for rehearing has not expired. We should hesitate to issue a mandate knowing that at the time it is issued we might have to recall it in order to entertain any petition for rehearing.

"Under Rule 62, Rules of Civil Procedure, two modes of procedure are open to the appellant neither of which involves a shortening of the time for the issuance of the mandate. Subdivision (c) of Rule 62 [8] authorizes the district court to grant an injunction during the pendency of an appeal. Subdivision

[8] "(c) Injunction pending appeal. When an appeal is taken from an interlocutory or final judgment, granting, dissolving, or denying an injunction, the court in its discretion may suspend, modify, restore, or grant an injunction during the pendency of the appeal upon such terms as to bond or otherwise as it considers proper for the security of the rights of the adverse party. If the judgment appealed from is rendered by a district court of three judges specially constituted pursuant to a statute of the United States, no such order shall be made except (1) by such court sitting in open court or (2) by the assent of all the judges of such court evidenced by their signatures to the order."

(g)[9] of the same Rule recognizes the power of this court to grant an injunction during the pendency of the appeal here.

"The motion of the United States is not, in terms, an application for an injunction by this court, and it should not be entertained as such a motion not only because it does not seek such relief but also because this court is not as well equipped as is the district court to enforce an injunction of the type here sought.[10] Because the United States may obtain an injunction pending the time until mandate shall have reached the district court upon application to that court under Rule 62 (c), we deny the motion that mandate be issued forthwith.

"It is of course generally the rule that when an appeal is perfected the district court loses jurisdiction to take further action in the cause, but subdivision (c) of Rule 62 is an exception to that general rule and a recognition of the long established right of the trial court, after an appeal, to make orders appropriate to preserve the *status quo* while the case is pending in the appellate court. Newton v. Consolidated Gas Co., 258 U. S. 165, 177.[11]

"Under old equity rule 74, 226 U. S. 670, the trial judge was permitted to make such an order when he allowed the appeal, 'at the time of such allowance.' Subdivision (c) of Rule 62, omits reference to any specific time when the district court may grant such an injunction, and we think that under common principles of construction, this authority of the district court must now be held to continue throughout the period when the appeal is pending. Such injunction must be supported by appropriate showing and findings. Mayflower Industries v. Thor Corporation, 182 F. 2d 800.

"Accordingly the motion that mandate be issued forthwith is denied without prejudice to the right of appellant hereafter to make application to this court for such further order as it may hereafter be advised to seek.

"For the reasons which we have herein expressed, appellees' motion for stay of mandate is denied."

In accordance with the foregoing opinion, a motion for a temporary restraining order was filed on July 5, 1951, with the United States District Court for the Southern District of California. On the same date, the motion was granted and a temporary restraining order issued temporarily enjoining the defendants in each of the consolidated cases from commission of the acts complained of.

On July 31, 1951, following receipt of the mandate of the appellate court, findings of fact and conclusions of law were filed in each case in accordance with the appellate court's opinion of June 18, 1951.

With respect to the case against the El-O-Pathic Pharmacy, a corporation, it was pointed out that the corporation was dissolved on September 7, 1949, and was no longer in existence; and, accordingly, the complaint for injunction was dismissed as to this defendant. On the same day, an order was entered permanently enjoining Martin A. Clemens and Vita Pharmacals, Inc., from violating Sections 301 (a) and 301 (k), by distributing *male or female sex hormones* misbranded under Sections 502 (a), 502 (f) (1), 502 (f) (2), or 502 (j).

The nature of the injunction entered in the case against the Hudson Products Co., et al., is set forth in notices of judgment on drugs and devices, No. 3553.

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[9] "(g) Power of Appellate Court Not Limited. The provisions in this rule do not limit any power of an appellate court or of a judge or justice thereof to stay proceedings during the pendency of an appeal or to suspend, modify, restore, or grant an injunction during the pendency of an appeal or to make any order appropriate to preserve the *status quo* or the effectiveness of the judgment subsequently to be entered."

[10] Cumberland Tel. Co. v. Pub. Serv. Comm., 260 U. S. 212, was a case in which the Supreme Court recognized its power to grant a temporary injunction but considered it more appropriate to refer the application to the trial court.

[11] The *status quo* which the action was brought to preserve, was the protection of the public against the sale of certain misbranded drugs. The decision of this court is to the effect that such relief should have been granted.

3551. Misbranding of Hydr-Oxy-Colon device. U. S. v. 1 Device * * * (and 5 other seizure actions). (F. D. C. Nos. 30923, 31341, 31376 to 31379, incl. Sample Nos. 90020–K, 90021–K, 15777–L to 15781–L, incl.)

LIBELS FILED: April 17 and July 12 and 24, 1951, District of Kansas.

ALLEGED SHIPMENT: On or about June 19 and 30, July 8, 10, 12, and 24, August 26, and September 15, 1950, from Dallas, Tex., Miami, Okla., and Hollywood, Calif., by or for the United X-Ray & Equipment Co., Inc., of Hollywood, Calif.

PRODUCT: 7 *Hydr-Oxy-Colon* devices at Garden City, Liberal, Pratt, Medicine Lodge, Jamestown, and Junction City, Kans., together with certain printed and graphic matter, namely, a number of booklets entitled "DeWelles 'Detoxacolon' Oxygen Therapy," "Our Logical and Cooperative Clinic Plan," treatment charts bearing directions for treating numerous organs and disease conditions with the device, a leaflet entitled "Compare! The Normal Colon With Cases Pictured Below," and copy for use in preparing newspaper advertising and postal cards.

The devices were designed for administering mixed oxygen and water as an enema or vaginal douche.

RESULTS OF INVESTIGATION: Each of the devices was delivered to the consignees pursuant to agreements with the United X-Ray & Equipment Co., Inc., of Hollywood, Calif. When received by the consignees, the name plate on a number of the devices bore the name "Detoxacolon." These name plates were removed from the devices after delivery to the consignees, by representatives of the United X-Ray & Equipment Co., Inc., and replaced with a plate bearing the designation "Hydr-Oxy-Colon."

At the time the contracts were entered into with the company, its representatives supplied the purchasers with suggested copy for newspaper advertising and suggested copy for postal cards announcing free examinations by the consignees, assisted by a diagnostic specialist from Los Angeles, Calif. Reference was made to "New Colon Oxygen Therapy" on the postal card and "Oxygen Therapy" and "This New Colon Therapy, Which Embodies The Use Of Pure Oxygen and Water" in the newspaper advertisement. In each instance, the consignee delivered to a local newspaper the copy for the newspaper advertisement.

In accordance with the contract, a clinic was held in the office of each consignee, at which a representative of the United X-Ray & Equipment Co., Inc., was present. The booklets, leaflets, and treatment charts were furnished to the consignees by the company's representatives either at the time the agreement between the company and the consignees was made or at the time of the delivery of the devices or the holding of the clinic.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and designs in the labeling accompanying the device were false and misleading. The statements and designs represented and suggested that the device was an adequate and effective treatment for allergy, asthma, hay fever, diabetes, arthritis, rheumatism, and high and low blood pressure; disorders of the kidney, ear, eustachian tube, eyes, thyroid, gall bladder, male and female reproductive organs, urinary bladder, pituitary, thymus, skin, rectum, lung, pancreas, adrenals, ovaries, testes, and colon; ptosis of liver, stomach, and colon; headaches, parasitic infestations, mineral deficiency, calcium deficiency, neuritis, colitis, including ulcerative and spastic types, varicosities,

stomach ulcers, heart conditions, including functional disorders, angina pectoris, partial heart block, and arrhythmias, spasticity of rectum, extreme ulceration of lower bowel, common cold, acute and chronic coryza, sinusitis, dysentery, amebic dysentery, flaccid condition of sphincters, anemia (pernicious and secondary), epilepsy, toxemias of pregnancy, infections and inflammations of female reproductive organs, prolapse of rectum and sigmoid, and enlargement of spleen and liver; that the device was an excellent treatment following childbirth; that it would eliminate distress and disease and would correct chronic ailments or pathological changes and bring about a restoration of health; and that the device was effective in the treatment of intestinal influenza, nausea, vomiting, extreme weakness, loss of weight, numerous daily bloody stools, displaced colon, projectile vomiting, inability to retain liquids, cancer, intestinal contraction, and adhesions. The device was not an adequate and effective treatment for such disease conditions, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (j), the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in the accompanying booklet entitled "DeWelles 'Detoxacolon' Oxygen Therapy," as follows:

"Vaginal Therapy The vaginal treatment is given for infections and inflammatory diseases of the female pelvis, and is unexcelled in the results obtained by exposing the mucous membrane to the bactericidal effects of Oxygen. The continuous flow of Oxygen and water coming into contact with the tiny million folds in the mucous membrane of the vaginal wall and cervix with its countless millions of capillaries, is stimulating and thoroughly cleanses each cell of this membrane. This produces an extremely rapid destruction of such organisms as the trichomonadiaes vaginalis. B. coli Staphylococcus and Streptococcus, which are the organisms usually found in these inflammatory conditions as well as cervical erosions. These conditions are usually manifest by vaginal discharges and tenderness in the pelvis upon pressure. The debris that is loosened by the action of this treatment, the secretion from stimulated mucous gland activity and the necrotic tissue fragments and shreds are carried away due to the action of the water during treatment. They are not left in the vaginal vault to further decompose or cause further inflammation and infection and which is equally serious—toxic absorption into the blood stream. This is in definite contrast to any other type of treatment now existing, and it produces a wholesome and exhilarating reaction upon all whom are fortunate enough to have this treatment. The only Contra-Indication for the vaginal treatment is during the early months of pregnancy. It is an excellent treatment following childbirth, as the tonus of these muscles is returned to normal much faster than in the usual period of time. INSTRUCTIONS FOR VAGINAL THERAPY PROCEDURE: * * * The operator * * * inserts the vaginal applicator * * * The suggested treating time is 20 to 25 minutes * * * Turn the water control valve about a quarter of a turn and adjust the temperature until 100° F. is reached. * * * Rapidly increase the temperature until tolerance has been reached, usually 115° F. for the first treatment. * * * establish a two (2) liter flow * * * Treat on the Hot water at tolerance for five (5) minutes * * * Turn the thermostat to the Cold until a temperature of 90° F. has been reached, and repeat the above procedure * * *. In cases where the vaginal area is highly inflamed, it may be necessary for the first few treatments to raise the temperature to 95° F. * * *. Treat for five (5) minutes on the Cold water. Rise the temperature again as rapidly as possible to the tolerance of patient, or back to 115° F., and repeat the treatment on the Hot water for five minutes then reduce to the Cold water and repeat treatment. The temperature should then be brought back to 100° F. and left running for a minute or so. * * * we advise giving three (3) treatments per week * * * keep in mind always the pathology of the case and the degree of infection present before lowering the temperature to 80° F."

The device was dangerous since in the post partum period and in the acute stages of vaginal infections, treatment as directed would force infective material into or through the cervical canal, resulting in ascending infection with probable serious consequences to the health of the patient.

The device was alleged to be misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: June 19 and September 24, 1951. Default decrees of condemnation. The court ordered that two of the devices be delivered to the Food and Drug Administration and that the remainder be destroyed.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3552. TB–1 tables. U. S. v. 4,682 Bottles, etc. (F. D. C. No. 30311. Sample No. 35716–K.)

LIBEL FILED: December 8, 1950, Northern District of California; amended libel filed May 31, 1951.

ALLEGED SHIPMENT: On or about April 24 and 26, and September 11, 1950, the American Cyanamid Co., Calco Chemical Div., Bound Brook, N. J., shipped to itself in Los Angeles, Calif., a quantity of TB–1 powder. On or about September 15 and 20, 1950, the powder was sold to a firm in San Francisco, Calif., which firm had it tableted and packed into bottles.

PRODUCT: 4,682 bottles of *TB–1 tablets* at San Francisco, Calif., together with a number of accompanying leaflets entitled "Reference Manual 601 TB1–PSL The New Antituberculous Drug."

LABEL, IN PART: (Bottle) "100 Tablets—1050 TBI–PSL * * * 50 Mgm. Per Tablet."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: August 28, 1951. The claimant having indicated that it did not desire to contest the matter, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3553. Action to enjoin and restrain violations of Section 301 (a) with respect to male and female hormones. U. S. v. Hudson Products Co. (Maywood Pharmacal Co.), and Allen H. Parkinson. Tried to the court. Judgment denying application for permanent injunction reversed upon appeal. (Inj. No. 218.)

COMPLAINT FILED: September 29, 1949, Southern District of California, against the Hudson Products Co., a corporation, Long Beach, Calif., also trading under the name of the Maywood Pharmacal Co., at Hollywood, Calif., and against Allen H. Parkinson, president of the Hudson Products Co.

ALLEGED VIOLATION: The complaint alleged that the defendants were distributors of certain *male and female hormones*; that the *male hormones* consisted of *methyltestosterone tablets* (10 milligrams), *methyltestosterone linguets*

*See also No. 3550.

(5 milligrams), and *methyltestosterone linguets combined with vitamin* B_1; and that the *female hormones* consisted of tablets containing 0.1 milligram *alpha-estradiol.*

The complaint alleged also that the defendants were violating Section 301 (a) of the Act by causing the introduction into interstate commerce of the 5 milligram *methyltestosterone linguets* and the *methyltestosterone linguets combined with vitamin* B_1, which were misbranded as follows:

Section 502 (a), the labeling of the linguets was false and misleading since the labeling represented and suggested that the recommended daily dosage was efficacious for use in the treatment of the male hormone deficiency, whereas the recommended daily dosage would be entirely ineffective for such purpose; Section 502 (f) (1), the labeling of the linguets failed to bear adequate directions for use since it failed to state all of the diseases or conditions of the body for which the drug was intended; and Section 502 (f) (2), the labeling of the linguets failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form, as are necessary for the protection of the user since the technical medical terminology in which the cautionary statement on the labeling was couched was inadequate to warn the ordinary lay user that their use may accelerate the malignant growth of the prostrate gland or may cause sterility.

It was alleged also with respect to the *methyltestosterone tablets* and the *alpha-estradiol* preparations that the defendants would likely cause the same violations of Section 301 (a) of the Act as they were causing with respect to the linguets since the defendants had sold in the past such products without a physician's prescription and without adequate warnings and since the unrestricted use of *alpha-estradiol* preparations by women may accelerate the malignant growth of cancer of the breast, cervix, and uterus, and may cause injury to the female generative system.

Disposition: On January 11, 1950, after a hearing on the issuance of a preliminary injunction, the application for such injunction was denied. The case then was consolidated with that against the El-O-Pathic Pharmacy, et al, reported in notices of judgment on drugs and devices, No. 3550. After the consolidated cases came on for trial before the court on January 31, 1950, judgment was rendered in such cases, denying the Government's application for permanent injunction. Upon appeal, the judgment was reversed and the cases were remanded to the district court for the entry of a decree of permanent injunction in each case.

On July 31, 1951, findings of fact and conclusions of law were filed, supporting the issuance of a permanent injunction, and on the same day an order was entered permanently enjoining the Hudson Products Co., the Maywood Pharmacal Co., and Allen H. Parkinson from violating Section 301 (a) by distributing male or female sex hormone drugs misbranded under Sections 502 (a), 502 (f) (1), or 502 (f) (2).

3554. Misbranding of Dexedrine Sulfate tablets. U. S. v. Rudolph Matlock (Matlock Pharmacy), and Homer T. Wyatt. Pleas of guilty. Fine of $1,000 against Defendant Matlock; fine of $500 against Defendant Wyatt. (F. D. C. No. 30589. Sample Nos. 54198–K, 85883–K, 86036–K to 86038–K, incl.)

Information Filed: July 17, 1951, Northern District of Texas, against Rudolph Matlock, trading as Matlock Pharmacy, Arlington, Tex., and against Homer T. Wyatt, a pharmacist employed by Rudolph Matlock.

INTERSTATE SHIPMENT: From the State of Pennsylvania into the State of Texas, of quantities of *Dexedrine Sulfate tablets.*

ALLEGED VIOLATION: On or about November 2, 7, 8, and 9, 1950, while the tablets were being held for sale at the Matlock Pharmacy after shipment in interstate commerce, various quantities of the tablets were repacked and sold without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

Rudolph Matlock, as owner, was made a defendant in all counts; and, in addition, Homer T. Wyatt was joined as a defendant in two of the counts involving sales made by him.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), a portion of the repackaged tablets failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: October 31, 1951. Pleas of guilty having been entered, the court imposed a fine of $1,000 against Defendant Matlock and a fine of $500 against Defendant Wyatt.

3555. Misbranding of Dexedrine Sulfate tablets. U. S. v. J. Malcolm Webb (Webb's Drugs). Plea of guilty. Fine, $250. (F. D. C. No. 30615. Sample Nos. 84778–K, 10855–L.)

INFORMATION FILED: July 17, 1951, Southern District of Ohio, against J. Malcolm Webb, trading as Webb's Drugs, Camden, Ohio.

INTERSTATE SHIPMENT: From the State of Pennsylvania into the State of Ohio, of quantities of *Dexedrine Sulfate tablets.*

ALLEGED VIOLATION: On or about November 3, 1950, and January 4, 1951, while the tablets were being held for sale at Webb's Drugs after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and sold without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged tablets bore no directions for use.

DISPOSITION: November 15, 1951. A plea of guilty having been entered, the court imposed a fine of $250.

3556. Misbranding of pentobarbital sodium capsules and Dexedrine Sulfate tablets. U. S. v. Frierson Drug Store (Frierson Drug Co., Inc.), Frederick J. Felder, and Harley S. Martin. Pleas of guilty. Fines of $100 against corporation and $50 against each individual. (F. D. C. No. 30036. Sample Nos. 81903–K, 81905–K, 81907–K, 81909–K, 81911–K, 81912–K.)

INFORMATION FILED: August 8, 1951, Eastern District of South Carolina, against the Frierson Drug Store, a corporation, trading as Frierson Drug Co., Inc., Charleston, S. C., and Frederick J. Felder, president, and Harley S. Martin, secretary-treasurer of the corporation.

ALLEGED SHIPMENT: From the States of Georgia and Pennsylvania into the State of South Carolina, of quantities of *pentobarbital sodium capsules* and *Dexedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about April 5, 14, 26, and 28, 1950, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The Frierson Drug Store was charged with causing the acts of repacking and sale of the drugs involved in each of the six counts of the information; and, in addition, Frederick J. Felder in each of five counts of the information and Harley S. Martin in one count of the information were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: August 8, 1951. Pleas of guilty having been entered, the court imposed fines of $100 against the corporation and $50 against each of the individuals.

3557. Misbranding of pentobarbital sodium capsules, Benzedrine Sulfate tablets, Dexedrine Sulfate tablets, and sulfadiazine tablets. U. S. v. Medley Drug Store and Raymond R. Medley. Pleas of guilty. Fine of $70 against defendants jointly. (F. D. C. No. 30568. Sample Nos. 76974-K, 76976-K, 77605-K, 77764-K, 77765-K, 77769-K, 78212-K.)

INFORMATION FILED: May 25, 1951, Western District of Missouri, against the Medley Drug Store, a partnership, Lebanon, Mo., and Raymond R. Medley, a partner in the partnership.

INTERSTATE SHIPMENT: From the States of Illinois and Pennsylvania into the State of Missouri, of quantities of *Pentobarbital sodium capsules*, *Benzedrine Sulfate tablets*, *Dexedrine Sulfate tablets*, and *Sulfadiazine tablets*.

ALLEGED VIOLATION: On or about May 21, June 12, and July 5, 8, and 12, 1950, while the drugs were being held for sale at the Medley Drug Store after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repacked drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Benzedrine Sulfate tablets, Dexedrine Sulfate tablets,* and *sulfadiazine tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged. *sulfadiazine tablets* bore no warning against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: October 1, 1951. Pleas of guilty having been entered, the court imposed a fine of $70 against the defendants jointly.

3558. Misbranding of pentobarbital sodium capsules, Dexedrine Sulfate tablets, thyroid tablets, diethylstilbestrol capsules, and sulfadiazine tablets. U. S. v. Burley F. Jones (Sidney's Drug Store), Jay J. Gentry, and Cecil N. Gammon. Pleas of guilty. Fine of $100 against defendants jointly. (F. D. C. No. 30566. Sample Nos. 76957–K, 76959–K, 76962–K, 76979–K, 77036–K, 77145–K, 77146–K, 77766–K, 77771–K, 78215–K.)

INFORMATION FILED: June 22, 1951, Western District of Missouri, against Burley F. Jones, trading as Sidney's Drug Store, Lebanon, Mo., and against Jay J. Gentry, an employee of the store, and Cecil N. Gammon, a pharmacist for the store.

INTERSTATE SHIPMENT: From the States of Illinois, Pennsylvania, and Michigan, into the State of Missouri, of quantities of *pentobarbital sodium capsules, Dexedrine Sulfate tablets, thyroid tablets, diethylstilbestrol capsules,* and *sulfadiazine tablets.*

ALLEGED VIOLATION: On or about May 21, June 12 and 17, and July 5, 6, and 12, 1950, while the drugs were being held for sale at Sidney's Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Burley F. Jones was charged with causing the acts of repacking and sale of the drugs involved in each of the ten counts of the information; and, in addition, Jay J. Gentry in each of two counts of the information and Cecil N. Gammon in one count of the information were charged with causing such acts to be done in conection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing the common or usual name of the drug.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion

of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warning against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: September 21, 1951. Pleas of guilty having been entered, the court imposed a fine of $100 against the defendants jointly.

3559. Misbranding of pentobarbital sodium capsules and Tuinal capsules. U. S. v. Carolina Pharmacy and T. Philip Lloyd. Pleas of nolo contendere. Fine of $500 against defendants jointly. Individual also placed on probation for 2 years. (F. D. C. No. 30588. Sample Nos. 81985–K, 82041–K, 82043–K, 82085–K, 82088–K.)

INFORMATION FILED: June 21, 1951, Middle District of North Carolina, against the Carolina Pharmacy, a partnership, Chapel Hill, N. C., and T. Philip Lloyd, a partner in the partnership.

INTERSTATE SHIPMENT: From the States of Georgia and Indiana into the State of North Carolina, of quantities of *pentobarbital sodium capsules* and *Tuinal capsules.*

ALLEGED VIOLATION: On or about July 17, September 27 and 29, and October 5, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), a portion of the repackaged *pentobarbital sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the drugs contained chemical derivatives or barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the label of the repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since the directions "Dose One" appearing on the labeling of a portion of the repackaged drugs were not adequate directions for use and since the labeling of the remainder of the repackaged drugs bore no directions for use.

DISPOSITION: September 24, 1951. Pleas of nolo contendere having been entered. the court imposed a fine of $500 against the defendants jointly and placed the individual defendant on probation for 2 years on the condition that he keep an accurate record of all sales of the drugs involved and have the records available for inspection at all times.

3560. Misbranding of diethylstilbestrol perles. U. S. v. Standard Pharmacy and Thomas L. White. Pleas of guilty. Fine of $150 against each defendant. (F. D. C. No. 30613. Sample No. 82195–K.)

INFORMATION FILED: July 19, 1951, Northern District of Georgia, against the Standard Pharmacy, a corporation, Atlanta, Ga., and Thomas L. White, president of the corporation.

INTERSTATE SHIPMENT: From the State of Michigan into the State of Georgia, of a quantity of *diethylstilbestrol perles.*

ALLEGED VIOLATION: On or about November 2, 1950, while the drug was being held for sale at the Standard Pharmacy after shipment in interstate commerce, the Standard Pharmacy and Thomas L. White caused a number of the *diethylstilbestrol perles* to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug bore no label containing the name and place of business of the manufacturer, packer, or distributor, or a statement of the quantity of the contents; Section 502 (e) (1), the repackaged drug bore no label containing the common or usual name of the drug; and, Section 502 (f) (1), the labeling of the repackaged drug bore no directions for use.

DISPOSITION: September 28, 1951. Pleas of guilty having been entered, the court imposed a fine of $150 against each defendant.

3561. Misbranding of dextro-amphetamine sulfate tablets and phenobarbital tablets. U. S. v. Alexander Canales, Sr., (West Dallas Drug Store), and Edmund L. Hall. Pleas of guilty. Fine of $1,000 against Defendant Canales and fine of $500 against Defendant Hall. Jail sentence of 6 months against each defendant suspended; each defendant placed on probation. (F. D. C. No. 30575. Sample Nos. 54210–K, 75121–K, 75123–K to 75126–K, incl.)

INFORMATION FILED: September 17, 1951, Northern District of Texas, against Alexander Canales, Sr., trading as the West Dallas Drug Store, Dallas, Tex., and Edmund L. Hall, a pharmacist in the drug store.

INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of Texas, quantities of *dextro-amphetamine sulfate tablets* and *phenobarbital tablets.*

ALLEGED VIOLATION: On or about July 7, 9, 11, and 13, 1950, while the drugs were being held for sale at the West Dallas Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

Alexander Canales, Sr., was charged with causing the acts of repacking and sale of the drugs involved in each of the 6 counts of the information; and, in addition, Edmund L. Hall was charged in one count with causing such acts to be done in connection with the drug involved in that count.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *phenobarbital tablets* and portions of the repackaged *dextro-amphetamine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged drugs bore no labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), a portion of the *dextro-amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: September 17, 1951. Pleas of guilty having been entered, the court imposed a fine of $1,000 against Defendant Canales and a fine of $500 against Defendant Hall. The court imposed also a sentence of 6 months in jail against each defendant, which was suspended, and placed each defendant on probation for 1 year.

3562. Misbranding of dextro-amphetamine sulfate tablets, methyltestosterone tablets, and d-desoxyephedrine hydrochloride tablets. U. S. v. Houston's Drug Store, Inc., and Glenn Jackson. Plea of nolo contendere for corporation and plea of guilty for individual. Fine of $250 against corporation; sentence of 1 year's imprisonment against individual. Individual's sentence suspended and this defendant placed on probation for 5 years. (F. D. C. No. 30016. Sample Nos. 63672–K, 63948–K, 81811–K, 81822–K, 81825–K.)

INFORMATION FILED: On or about January 2, 1951, Southern District of Florida, against Houston's Drug Store, Inc., Jacksonville, Fla., and Glenn Jackson, secretary-treasurer of the corporation.

INTERSTATE SHIPMENT: From the States of Pennsylvania, New Jersey, and New York, into the State of Florida, of quantities of *dextro-amphetamine sulfate tablets*, *methyltestosterone tablets*, and *d-desoxyephedrine hydrochloride tablets*.

ALLEGED VIOLATION: On or about April 10, 25, 27, and 29, and May 1, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused one bottle of *methyltestosterone tablets* to be sold and disposed of to a purchaser in the original bottle in which the tablets had been shipped in interstate commerce, without the prescription of a physician; and the defendants repacked various quantities of *dextro-amphetamine sulfate tablets* and *d-desoxyephedrine hydrochloride tablets* and sold the repackaged drugs without prescriptions, which acts of the defendants resulted in the drugs being misbranded.

NATURE OF CHARGE: *Methyltestosterone tablets.* Misbranding, Section 502 (f) (1), the labeling of the drug bore no directions for use. (The bottle in which the tablets were shipped in interstate commerce bore no directions for use since it was exempted from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendants in dispensing the drug without a physician's prescription, however, caused the exemption to expire.)

Dextro-amphetamine sulfate tablets and *d-desoxyephedrine hydrochloride tablets.* Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

Further misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents since the label of a portion of the repackaged *d-desoxyephedrine hydrochloride tablets* bore the statement "100," whereas the bottle contained less than 100 tablets; and the remainder of the repackaged *d-desoxyephedrine hydrochloride tablets* and the *dextro-amphetamine sulfate tablets* bore no labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (b) (1), the repackaged *dextro-amphetamine sulfate tablets* and a portion of the repackaged *d-desoxyephedrine hydrochloride tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (1), they failed to bear labels containing the common or usual name of the drugs.

DISPOSITION: July 20, 1951. A plea of nolo contendere having been entered on behalf of the corporation and a plea of guilty on behalf of the individual, the court imposed a fine of $250 against the corporation and a sentence of 1 year's imprisonment against the individual. The sentence against the individual was suspended, and he was placed on probation for five years.

3563. Misbranding of sulfathiazole tablets. U. S. v. David Polis (Polis Pharmacy). Plea of nolo contendere. Fine of $500 on count 1. Sentences of 6 months in jail on each of counts 2 and 3; jail sentences suspended. (F. D. C. No. 30033. Sample Nos. 48680–K, 81266–K, 81271–K.)

INFORMATION FILED: February 19, 1951, Eastern District of Pennsylvania, against David Polis, trading as Polis Pharmacy, Philadelphia, Pa.

INTERSTATE SHIPMENT: From the State of New York into the State of Pennsylvania, of quantities of *sulfathiazole tablets*.

ALLEGED VIOLATION: On or about June 23, 26, and 29, 1950, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the tablets to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear labels containing the common or usual name of the drug; and, Section 502 (f) (1), the labeling of the repackaged tablets bore no directions for use.

DISPOSITION: July 12, 1951. A plea of nolo contendere having been entered, the court imposed a fine of $500 on count 1 and sentences of six months in jail on each of counts 2 and 3. The jail sentences were suspended.

3564. Misbranding of sulfathiazole tablets. U. S. v. Isaac Russikoff (Russikoff's Drug Store). Plea of nolo contendere. Fine of $500 on count 1. Sentences of 6 months in jail on each of counts 2 and 3; jail sentences suspended. (F. D. C. No. 30034. Sample Nos. 81267–K, 81270–K, 81272–K.)

INFORMATION FILED: February 19, 1951, Eastern District of Pennsylvania, against Isaac Russikoff, trading as Russikoff's Drug Store, Philadelphia, Pa.

INTERSTATE SHIPMENT: From the State of New York into the State of Pennsylvania, of quantities of *sulfathiazole tablets*.

ALLEGED VIOLATION: On or about June 23, 26, and 29, 1950, while the drug was being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drug to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged tablets failed to bear a label

containing the common or usual name of the drug, i. e., sulfathiazole; and, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use of the drug.

DISPOSITION: July 12, 1951. A plea of nolo contendere having been entered the court imposed a fine of $500 on count 1 and sentences of 6 months in jail on each of counts 2 and 3. The jail sentences were suspended.

3565. Misbranding of No. 29 tablets and No. 367 tablets. U. S. v. 10 Jars, etc. (F. D. C. No. 30788. Sample No. 23694-L.)

LIBEL FILED: March 2, 1951, District of Connecticut.

ALLEGED SHIPMENT: On or about October 12, 1950, by the Buffalo Pharmacal Co., from Buffalo, N. Y.

PRODUCT: 10 1,000-tablet jars of *No. 29 tablets* and 10 1,000-tablet jars of *No. 367 tablets* at Madison, Conn., in possession of the Shore Chemical Co.

RESULTS OF INVESTIGATION: The tablets were shipped by the Buffalo Pharmacal Co. to a consignee at Madison, Conn., and were delivered by the consignee to the Shore Chemical Co. In addition to the tablets, there were in possession of the Shore Chemical Co., a stock of labels reading "Arpane Pain Tablets" which were for use in repackaging the *No. 29 tablets* and a stock of labels reading "Arpane Treatment Tablets" which were for use in repackaging the *No. 367 tablets*.

LABEL, IN PART: (Jar) "No. 29 xx 1000 Tablets xx Acetophenetidin Aspirin Caffeine Pink xx Acetophenetidin – 2½ grs. Aspirin – 2½ grs. Caffeine Alkaloid – ¼ gr. xx Warning: Contains Acetophenetidin. Frequent or continued use may be dangerous, causing serious blood disturbances. Do not take more than the dosage recommended. Caution: To be dispensed only by or on the prescription of a physician. Manufactured for Buffalo Pharmacal Company, Inc. Buffalo, N.Y." and "No. 367 xx 1000 Tablets Mixed Treatment CCT xx Mercury Bichloride – 1/64 gr. Potassium Iodide – 2 gr. Ferrous Iodide – 0.436 gr. Arsenous Iodide – 0.019 gr. Mercuric Iodide – 0.019 gr. Powdered Extract Nux Vomica – 0.0315 gr. (Representing Tincture Nux Vomica, 2 min. containing Strychnine .00218 gr.) xx Warning: Contains Arsenic, Mercury, Iodide and Strychnine. Excessive dosage is dangerous. The prolonged use of this preparation or the use of amounts in excess of the prescribed directions may cause serious mercury poisoning. Do not use in tuberculosis or thyroid disease, except under the direction of a physician. Caution: To be dispensed only by or on the prescription of a physician. Manufactured for Buffalo Pharmacal Company, Inc. Buffalo, N. Y."

NATURE OF CHARGE: *No. 29 tablets.* Misbranding Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use. The tablets were misbranded in this respect when introduced into and while in interstate commerce.

No. 29 tablets and *No. 367 tablets.* Misbranding, Section 502 (a), the following statements on the jar labels used in repackaging the tablets were false and misleading since the tablets were not effective in the relief or treatment of the conditions stated and implied: (No. 29 – Arpane Pain Tablets) "* * * for Relief in Arthritis and Rheumatism * * * This preparation combines the best known chemicals for the relief of suffering due to Arthritis and Chronic Rheumatism by lowering the temperature, lessening the swelling, reducing acidity and stimulating the blood vessels * * *" and (No. 367 – Arpane Treatment Tablets) "Treatment for Arthritis and

Rheumatism * * * This preparation combines the best known chemicals for the treatment of Arthritis and Rheumatism. It aids in building up blood cells, improving the quality of the blood, absorbing inflammatory matter, increasing stomach functions, stimulating intestinal muscles, aiding digestion, improving the appetite and reducing the need for sedatives * * *." The tablets were misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 18, 1951. Default decree of condemnation and destruction.

3566. Misbranding of Dr. Means' Pills. U. S. v. 20 Dozen Boxes * * *. (F. D. C. No. 29091. Sample No. 13717–K.)

LIBEL FILED: May 1, 1950, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 1, 1949, from Buffalo, N. Y.

PRODUCT: 20 dozen boxes, each containing 30 pills, of *Dr. Means' Pills* at Lebanon, Pa., in possession of the Dr. W. B. Means Co. The pills were repackaged into boxes by the consignee from a bulk shipment.

LABEL, IN PART: "Dr. Means' Pills Each pill contains Strychnine Sulphate 1/200 gr., Acetanilid 1½ gr., with Caffeine Alkaloid and Camphor."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users since the article contained acetanilid and strychnine, and its labeling failed to warn that frequent or continued use may be dangerous, causing serious blood disturbances, anemia, collapse, or a dependence on the drug; that not more than the dose recommended should be taken; that the article should not be given to children; and that its use by elderly persons may be dangerous. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 18, 1951. The Dr. W. B. Means Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3567. Misbranding of Halox Therapeutic Generator. U. S. v. 22 Devices * * *. Tried to the court. Decree of condemnation. (F. D. C. No. 24848. Sample No. 31725–K.)

LIBEL FILED: May 20, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about April 30, May 9 and 14, July 24, and December 3, 1947, by the Halox Therapeutic Generator Co., from Central, N. Mex.

PRODUCT: 22 devices known as *Halox Therapeutic Generator* at Los Angeles, Calif. Examination showed that the device was designed to produce chlorine gas by means of electrolysis.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the conditions for which it was intended, and it failed also to bear adequate directions for use by reason of its failure to state all of the disease conditions for which the article was intended, namely, arthritis, sinusitis, hay fever, bronchitis, neuritis, sciatica, rheumatism, asthma, and nervous disorders.

DISPOSITION: Albert P. Mracek, trading as the Halox Therapeutic Generator Co., claimant, having filed an answer denying that the devices were misbranded, the case came on for trial before the court on the basis of a stipulated record. After consideration of the evidence and the briefs of counsel, the court, on July 27, 1951, handed down the following opinion:

BYRNE, *District Judge:* "This proceeding in rem was instituted by the United States pursuant to the provisions of the Federal Food, Drug and Cosmetic Act, 52 Statutes 1040, 21 U. S. C. A., section 301 et seq., seeking a decree condemning 22 devices, more or less, labeled in part 'Halox Therapeutic Generator.' The particular authority for this action is to be found in section 334 (a) of 21 U. S. C. A., which provides in part:

> (a) Any article of food, drug, device, or cosmetic that is . . . *misbranded* when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, *or at any time thereafter,* on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found . . . [Emphasis added.]

"It is the libelant's position that the 22 articles of device (hereinafter referred to as the 'devices' or 'generators') are liable to condemnation in that the generators were misbranded when introduced into, and while in, interstate commerce.

"These generators are devices for the electrolysis of sodium chloride (salt) solution. The device is housed in a leatherette-covered plywood cabinet, its base being approximately 12 inches by 15 inches, and its height approximately 12 inches. At the front of the cabinet is a control panel. Inside the cabinet there is placed a glass jar which is partly filled with a saturated sodium chloride (salt) solution. Carbon electrodes extend into this solution. When the generator is in operation, electricity is carried to these electrodes. As a result of the electrolysis of the salt solution, chlorine gas is produced. A small electric fan blows a current of air through the jar and out through a rubber hose. Thus a mixture of air and chlorine gas goes into the tube. This mixture is then administered to the person receiving the treatment known as 'chlorine inhalation therapy.' This is accomplished by having the patient hold the rubber tube to his nose and inhale the mixture.

"Subsequent to the filing of the libel, a monition issued directing the United States Marshal to seize the generators. In pursuance thereof the generators were seized and notice thereof was published, along with notice to all persons interested in said generators to present their claims to this court.

"One Albert P. Mracek, doing business as Halox Generator Company, appeared and made claim to the generators. Thereafter the claimant filed an answer denying that the generators were misbranded when introduced into, or while in, interstate commerce. The answer also sets up an affirmative defense designed to bring these devices within the administrative exemptions which will be discussed below. There is presently pending in the State of New Mexico an action contesting Mracek's ownership of these generators, but it has been stipulated that, for the purpose of the present action, Mracek shall be deemed to be the proper party claimant.

"21 U. S. C. A. sec. 321 (h) defines a device as follows:

> (h) The term "device" (except when used in paragraph (n) of this section and in sections 331 (i), 343 (f), 352 (c) and 362 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

"21 U. S. C. A. section 352 provides:

> A drug or device shall be deemed to be misbranded . . . (f) unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where

any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Administrator shall promulgate regulations exempting such drug or device from such requirements.

"Pursuant to the proviso of the above sub-section, the Administrator has promulgated certain regulations which may exempt devices from the requirement that they bear adequate directions for use. The regulation pertinent to this case is to be found in 21 C. F. R., section 1.106 (e) which provides:

(e) Except as otherwise provided by paragraphs (h) and (i) of this section, a shipment or other delivery of a drug or device also shall be exempt from the requirements of section 502 (f) (1) of the act, (21 U. S. C. A. sec. 352 (f) (1)) if it complies with all the conditions set forth in paragraphs (b) (3) and (6) of this section and if such shipment or delivery is made to a physician, dentist, veterinarian, hospital, or clinic to be dispensed by or under the direction of physicians, dentists, or veterinarians in their professional practices.

"Paragraph (b) (3), referred to in the above regulation, requires that information adequate for the use of such device by physicians, dentists, or veterinarians must be readily available.

"The regulations in section 1.106(k) (2) define a 'physician' as follows:

The terms "physician," "dentist," and "veterinarian," as used in relation to the exemption of any drug or device, include only those physicians, dentists, and veterinarians who are licensed by law to administer or apply such drug or device.

"From this statement of the pertinent provisions of the Act and Regulations we may now turn to the facts as stipulated to by the parties, to ascertain whether the generators bore adequate directions for use or, if not, whether they were exempt from such requirement by virtue of the above-quoted regulations.

"All twenty-two generators, which have been libelled, were manufactured by the Halox Therapeutic Generator Company, at Central, New Mexico. They were transported from New Mexico to California at various times during the year 1947, and were seized within the County of Los Angeles, California, in May 1948. No written, printed or graphic matter accompanied any of the generators except for the following statements on a metal plate affixed to each generator:

Patent No. 2256212
Other patents pending
Type . . . . No. 704
Halox Therapeutic Generator Co.
Scientific Chlorine Inhalators
Volts 110 Amps. Cyc. 60
Central, New Mexico, U. S. A.

"All, save one, of these devices were shipped to Dr. W. G. Keys, D. C., who held a valid license as a chiropractic doctor from the State of California. Dr. Keys maintained several offices in Los Angeles County at which these devices were used by him in his practice. The remaining generator was in the possession of another chiropractor, Dr. C. J. Henaghan, D. C. On December 1, 1947, Dr. Keys leased his practice, offices, and equipment to three lessees, one of whom was Dr. Henaghan, and these lessees were in possession of the generators at the time they were seized.

"Prior to December 1947, the Halox Therapeutic Generator Company was owned by Reverend Roger Aull. Father Aull also founded and owned a second organization known as the 'Father Aull Foundation.' The company manufactured the generators and the Foundation promoted the distribution of them. The devices which were shipped to Dr. Keys were *leased* to him under a printed lease agreement bearing the name of the Father Aull Foundation, but which actually designated Reverend Roger Aull as the lessor.

"A bill of sale of the Halox Therapeutic Generator Company, including the devices involved here, was executed by Reverend Roger Aull in favor of the claimant, Mracek, under date of December 1, 1947. This bill of sale was to be effective as of its date, but was not delivered to Mracek until after final shipment of generators to Dr. Keys on December 3, 1947.

"The record contains the following stipulation: 'The parties agree that the devices under seizure were intended for use in the conditions of arthritis, sinusitis, hay fever, and bronchitis.' The libelant also contends that the generators were intended for use in other conditions, namely, neuritis, sciatica, rheumatism, asthma, nervous disorders, ovarian conditions, prostate trouble, and allergies. The claimant denies this contention. The government bases its position on the fact that the Father Aull Foundation, in its lease agreement with Dr. Keys, reserved the power to control all advertising. Samples of the advertising disseminated by the chiropractors using the seized devices are a part of the record. Such advertisements show that the generators were advertised as being appropriate for the treatment of the conditions mentioned above. The failure of the Father Aull Foundation to object to such advertising, which it had reserved the power to control, is convincing evidence that the generators were intended for use in such conditions.

"At the outset it is clear that the generators did not bear adequate directions for use. In fact they bore no directions for use. This much is admitted by the claimant who rests his case on the proposition that the devices were exempt from this requirement by virtue of the exemption regulations set out above. It is the claimant's position that the devices were shipped or delivered to physicians to be dispensed by physicians in their professional practice. It is at once apparent that the claimant can succeed only if a chiropractor is a 'physician' within the meaning of the regulations.

"As was pointed out earlier, the regulation provides that the term 'physician' includes only those physicians who are licensed by law to administer or apply the drug or device in question. Thus, the persons to whom the devices were shipped must, first of all, be physicians. Only if they be physicians is it necessary to inquire into the matter of their authority to administer or apply the device.

"In its broadest sense the term 'physician' includes anyone exerting a remedial or salutary influence; as a physician of the soul. However, I do not believe the term as used in the regulation was intended in the broad sense. In Webster's New International Dictionary (unabridged), 2nd ed., 1949, one definition of 'physician' is: 'A person skilled in physic or the art of healing.' In the same volume 'chiropractic' is defined as: 'A system for the practice of adjusting the joints, especially at the spine, by hand, for the curing of disease.' Thus a chiropractor is one skilled in the art of healing, in a limited manner, although not one skilled in physic, since this latter term refers to the practice of medicine. In Webster's Dictionary, supra, a second definition of 'physician' is: 'one duly authorized to treat diseases especially by medicines; *a doctor of medicine*; often distinguished from a surgeon.' [Emphasis added.] Section 15 of the Chiropractic Law of the State of California, Deering's General Laws, 1944 ed., Act 4811; provides in part: '. . . any licensee under this act who uses . . . *the term "physician,"* . . . or any other letters, prefixes or suffixes, the use of which would indicate that he or she was practicing a profession for which he held no license from the state of California, . . . shall be guilty of a misdemeanor . . .' [Emphasis added.] It follows that one who is licensed to practice chiropractic in the state of California is not a physician by virtue of such license. The record is devoid of any evidence attributing qualifications as physicians to the chiropractors concerned here.

"There is, in addition, a more compelling reason for holding that the seized generators were not exempt from the requirement that they bear adequate directions for use. The exemption regulations define a physician as a physician who is licensed by law to administer or apply the drug or device in question. Thus, even if the term 'physician' is broad enough to include chiropractors, it includes only those chiropractors who are licensed by law to administer or apply the drug or device.

"The authority of a licensed chiropractor is defined by section 7 of the Chiropractic Law, supra, which provides:

> sec. 7. Certificate to practice. One form of certificate shall be issued by the board of chiropractic examiners, which said certificate shall be designated "License to practice chiropractic," which license shall authorize the holder thereof to practice chiropractic in the state of California as taught in chiropractic schools or colleges; and, also, to use all necessary mechani-

cal, and hygienic and sanitary measures incident to the care of the body, but shall not authorize the practice of medicine, surgery, osteopathy, dentistry or optometry, nor the use of any drug or medicine now or hereafter included in materia medica.

"The scope of this authority has not been defined by the Supreme Court of California, but other appellate courts of the state have had occasion to consider the question. In *People* v. *Fowler*, 32 Cal. App. Supp. 737, 84 P. 2d 326, the court first considered the meaning of the authorization 'to practice chiropractic . . . as taught in chiropractic schools or colleges.' The court held that this section authorized licensees to practice chiropractic as taught in chiropractic schools or colleges *at the time of the enactment of the Chiropractic Law.* The court observed that the term 'chiropractic' had a well-established and quite definite meaning when the statute was enacted, that is, that chiropractic is a system for the practice of adjusting the joints, especially at the spine, by hand, for the curing of disease. The court further held that the words 'as taught in chiropractic schools or colleges' did not set at large the meaning of 'chiropractic' and thereby leave the schools and colleges free to enlarge its meaning by changes in their curriculum. It at once is obvious that chlorine gas inhalation therapy administered by a machine does not fall within the meaning of 'chiropractic' as set out above, since it in no way involves the manipulation of joints by hand or otherwise. Furthermore the record contains the affidavits of two licensed chiropractors who are presently engaged in the training of students at the Los Angeles College of Chiropractic. One affiant is the Dean of the College and the other is the Director of the College Clinic. Both state that they do not know of any school of chiropractic that teaches or has taught chlorine gas inhalation therapy.

"However, section 7 of the Chiropractic Law contains a further authorization, namely, 'to use all necessary mechanical, and hygienic and sanitary measures incident to the care of the body.' In People v. Fowler, supra, the court held that this phrase 'is not a definition of, but an addition to, chiropractic as used in the previous part of section 7 and authorizes chiropractors to use measures which would not otherwise be within the scope of their licenses.'

"*In Re Hartman*, 10 Cal. App. 2d 213, 51 P. 2d 1104, the court, in referring to this clause stated:

> . . . that clause of the section refers to general hygienic and sanitary measures, even though mechanical, *and not to the treatment of diseases and ailments.* [Emphasis added.]

"Thus it is clear that a chiropractor licensed by the State of California is not authorized to treat diseases and ailments by mechanical means. As we have seen, the parties are agreed that the generators under seizure were intended for use in the conditions of arthritis, sinusitis, hay fever, and bronchitis. Furthermore, I find that the devices were intended for use in other conditions. All these conditions, admitted or disputed, are diseases and as such could not be treated by chiropractors by means of the Halox Therapeutic Generator. It follows that the seized generators were not exempted by the regulations since they were not shipped to physicians who were licensed by law to administer them.

"There is yet a third reason why the seized devices were not exempted by the administrative regulations. Those regulations require that information adequate for the use of such device by physicians be readily available. The record includes the results of an experiment conducted by Mr. Louis C. Weiss, a chemist employed by the Food and Drug Administration. The purpose of the experiment was to determine the chlorine concentration of the output of one of the seized devices at various dial settings. The generator was operated at each such varied dial setting for approximately three hours and the chlorine output was measured six times during each three hour test. In all, some eleven different tests were conducted, each at a different setting. It was Mr. Weiss' conclusion that it 'was impossible to set the dials and provide for a constant output of chlorine'. He stated further, 'For instance, during a typical run, the chlorine output varied in a two-hour period from 407.0 to 12.2 parts per million, a variation of 3300%, although the dial settings were unchanged.'

"The record also includes the affidavit of Dr. Clinton Hobart Thienes, M. D., chairman of the Department of Pharmacology at the University of Southern California Medical School. Dr. Thienes states that the use of chlorine gas in an effective antiseptic concentration would be too irritating to be withstood by the average individual and that concentrations less than this are ineffective for any purpose. He states further that chlorine gas to be safely inhaled for even a short time requires a concentration of less than ten parts per million. The results of Mr. Weiss' test show that a constant output of such a safe amount was obtained at only two dial settings. Yet nowhere in the record is it shown that directions were available suggesting such dial settings. Furthermore, at these settings the chlorine output varied throughout the three hour period. Thus it is clear that adequate directions were not available for the use of the generators.

"Dr. Thienes stated that on the basis of the Weiss affidavit he was of the opinion that it would be extremely difficult to regulate the output of the Halox Therapeutic Generator to consistently elicit a safe output of chlorine. He further stated: 'I would consider the Halox Therapeutic Generator as being incapable of effective operation in the treatment of any disorder *and would consider that it would be impossible to devise for it any adequate directions for use.*'

"It is not necessary to determine whether adequate directions could be devised, although that possibility may be doubted. It is certain, however, that adequate directions were not available to the persons to whom the seized generators were shipped.

"The twenty-two devices, more or less, labeled in part 'Halox Therapeutic Generator' must be condemned and disposed of by destruction in accordance with the provisions of 21 U. S. C. A., Sec. 334 (d). Libelant shall recover its costs.

"Libelant is requested to prepare findings of fact and conclusions of law in conformity with this opinion."

In accordance with the foregoing opinion, findings of fact and conclusions of law were handed down. On September 11, 1951, judgment of condemnation was entered, and the court ordered that 3 of the devices be delivered to the Food and Drug Administration and that the remainder of the devices be destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3568. Adulteration of Fleaseed husks (Plantago). U. S. v. 12 Bags * * *. (F. D. C. No. 30931. Sample No. 23904-L.)

LIBEL FILED: April 17, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about October 23, 1950, from India.

PRODUCT: 12 92-pound bags of *fleaseed husks* at Brooklyn, N. Y. Fleaseed is another name for the drug, Plantago.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 21, 1951. Default decree of condemnation and destruction.

3569. Adulteration of psyllium seed husks. U. S. v. 67 Bags * * *. (F. D. C. No. 30933. Sample No. 23917-L.)

LIBEL FILED: April 19, 1951, Eastern District of New York.

ALLEGED SHIPMENT: From India, arriving on or about November 21, 1950.

PRODUCT: 67 92-pound bags of *psyllium seed husks* at Brooklyn, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The

article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 21, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3570. Adulteration and misbranding of Hemoplex and Livofer-B. U. S. v. Bellevue Laboratories, Inc., and Chaim Dick. Pleas of guilty. Fine of $250 against corporation. Imposition of sentence against individual suspended and individual placed on probation for 1 year. (F. D. C. No. 29457. Sample Nos. 73652–K, 73666–K.)

INFORMATION FILED: September 24, 1951, Southern District of New York, against Bellevue Laboratories, Inc., New York, N. Y., and Chaim Dick, president-treasurer of the corporation.

ALLEGED SHIPMENT: On or about January 19, 1950, from the State of New York into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity of the articles fell below that which they purported and were represented to possess, in that the articles were not sterile and were not suitable for intramuscular injection since they were contaminated with viable sporeforming bacteria.

Misbranding, Section 502 (a), the statement "Sterile * * * For Intramuscular Use" displayed upon the label of the *Hemoplex* and the statement "Sterile * * * Intramuscular" displayed upon the label of the *Livofer-B* were false and misleading. Such statements represented and suggested that the articles were sterile and suitable for intramuscular injection, whereas the articles were not sterile and suitable for intramuscular injection since they were contaminated with viable sporeforming bacteria.

DISPOSITION: November 13, 1951. Pleas of guilty having been entered, the court imposed a fine of $250 against the corporation and suspended the imposition of sentence against the individual defendant and placed him on probation for 1 year.

3571. Adulteration and misbranding of estrogenic substances. U. S. v. Estro Chemical Co., Inc., and Harold H. London. Pleas of guilty. Fine of $800 against corporation. Imposition of sentence against individual suspended and individual placed on probation for 1 day. (F. D. C. No. 29430. Sample Nos. 11258–K, 11271–K, 15268–K, 52365–K, 62874–K, 62876–K.)

INFORMATION FILED: September 10, 1951, Southern District of New York, against the Estro Chemical Co., Inc., New York, N. Y., and Harold H. London, president of the corporation.

ALLEGED SHIPMENT: On or about September 10 and November 11 and 24, 1948, and August 15, 1949, from the State of New York into the States of New Jersey, Tennessee, Illinois, and Massachusetts.

LABEL, IN PART: "Aqua-Gyne Aqueous Estrogenic Substance 20,000 I. U. per cc." and "Aqueous Estrogyne 20,000 I. U."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, in the following respects: A number of the vials in two of the shipments of *Aqua-Gyne* con-

tained less than 97 percent of the amount of ketosteroids necessary to produce a potency of 20,000 International Units of estrone per cubic centimeter, and some vials in one of the shipments of *Aqua-Gyne* contained less and some vials contained more than 97 percent of the amount of ketosteroids necessary to produce a potency of 20,000 International Units of estrone per cubic centimeter. The *Aqueous Estrogyne* possessed a potency of less than 20,000 International Units of estrone activity per cubic centimeter.

Misbranding, Section 502 (a), the *Aqua-Gyne* label statement "Each cc. * * * contains * * * (Ketosteroids as Estrone, approximately 97% by potency) * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" and the *Aqueous Estrogyne* label statement "1 cc. Aqueous Estrogyne 20,000 I. U. Estrone per cc." were false and misleading.

DISPOSITION: November 13, 1951. The corporation having entered a plea of guilty to the 8 counts of the information and the individual having entered a plea of guilty to the 6 counts of the information in which he was charged as a defendant, the court imposed a fine of $800 against the corporation and suspended the imposition of sentence against the individual and placed him on probation for 1 day.

3572. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Drum * * *. (F. D. C. No. 30965. Sample No. 19252–L.)

LIBEL FILED: June 27, 1951, District of Minnesota.

ALLEGED SHIPMENT: On or about April 12, 1951, by the Keith Victor Pharmacal Co., from St. Louis, Mo.

PRODUCT: 1 drum containing 23,850 tablets of *conjugated estrogens* at Minneapolis, Minn. Analysis showed that the product contained a total amount of estrogenic steroids calculated as 0.82 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Sugar Coated Estrogen 1.25 Mg. tablets each tablet contains naturally occurring water-soluble conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement "each tablet contains naturally occurring water-soluble conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate" was false and misleading since the biological activity of the article was less than that declared.

DISPOSITION: September 5, 1951. Default decree of destruction.

3573. Adulteration and misbranding of conjugated estrogens. U. S. v. 3 Bottles * * *. (F. D. C. No. 31220. Sample No. 813–L.)

LIBEL FILED: June 27, 1951, Southern District of Florida.

ALLEGED SHIPMENT: During or about December 1950, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: 3 1,000-tablet bottles of *conjugated estrogens* at Miami Beach, Fla. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.59 milligram of sodium estrone sulfate per tablet.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of

estrogens in their naturally occurring water-soluble form, expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mg. of estrogens in their naturally occurring water soluble form, expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained less than the stated amount of estrogens.

DISPOSITION: August 17, 1951. Default decree of forfeiture and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3574. Misbranding of conjugated estrogens. U. S. v. 1 Bottle * * *. (F. D. C. No. 30960. Sample No. 13099–L.)

LIBEL FILED: June 30, 1951, Northern District of Texas.

ALLEGED SHIPMENT: On or about March 8, 1951, by the Spartan Pharmaceutical Co., from New York, N. Y.

PRODUCT: 1 1000-tablet bottle of *conjugated estrogens* at Lubbock, Tex.

LABEL, IN PART: "Spartan Conjugated Estrogens."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 Mg. of Estrogens in their naturally occurring water soluble conjugated form expressed as Sodium Estrone Sulfate" was false and misleading as applied to an article which contained 0.78 mg. of total estrogenic steroids calculated as sodium estrone sulfate.

DISPOSITION: October 24, 1951. Default decree of condemnation and destruction.

3575. Misbranding of Dolcin. U. S. v. 164 Cartons * * *. (F. D. C. No. 27355. Sample No. 13531–K.)

LIBEL FILED: June 23, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about May 11, 1949, by the Dolcin Corp., from Buffalo, N. Y.

PRODUCT: 164 cartons, each containing 1 bottle, of *Dolcin*, a leaflet entitled "Dolcin," and a business reply card at Trenton, N. J. Analysis indicated that the product consisted essentially of aspirin, 2.6 grains, and calcium succinate, 3.4 grains.

LABEL, IN PART: (Bottle) "Dolcin For Relief of Symptoms Arthritis Rheumatism Dolcin Corporation, New York, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle and carton labels, on the business reply card, and in the leaflet were false and misleading. The statements represented and suggested that the article was adequate and effective for the treatment and cure of rheumatism and arthritis, whereas the article was not effective for such purposes.

DISPOSITION: October 2, 1951. The Dolcin Corp., claimant, having filed an answer denying that the product was misbranded and later having been permitted to withdraw its claim and answer with the understanding that such withdrawal should not be deemed to constitute an admission of the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be destroyed.

*See also Nos. 3550, 3551, 3553, 3565, 3570–3573.

3576. Misbranding of Delcreo emulsion and Delcreo soluble sulfur compound capsules. U. S. v. 39 Bottles, etc. (and 1 other seizure action). (F. D. C. No. 30871. Sample Nos. 28996-L to 28999-L, incl.)

LIBELS FILED: April 5, 1951, District of Oregon.

ALLEGED SHIPMENT: On or about January 19, 1951, by Delson Chemical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 39 4-ounce bottles and 56 2-ounce bottles of *Delcreo emulsion* and 25 50-capsule boxes and 25 25-capsule boxes of *Delcreo soluble sulfur compound capsules* at Portland, Oreg.

LABEL, IN PART: (Bottle) "Delcreo * * * An Emulsion containing Creosote Carbonate (Delson), Calcium Hypophosphites, Sodium Hypophosphites, Potassium Hypophosphites. Improved Formula with Thiamin Hydrochloride, Vitamin B_1 Added" and (box) "Delcreo Soluble Sulphur Compound Capsules Active ingredient, sulphur in the form of sulphides."

NATURE OF CHARGE: *Delcreo emulsion.* Misbranding, Section 502 (a), certain statements on the label of the article, in an accompanying circular entitled "Delcreo * * * Improved Formula," and in a leaflet entitled "Delcreo 'Tone Up' Twins for Your Dog or Cat" were false and misleading. The statements represented and suggested that the article was effective to assist and stimulate the natural forces of the body; that it was a tonic and conditioner; that it was an effective treatment for infectious diseases of dogs, cats, and foxes, including bronchitis, catarrah, colds, diarrhea, distemper, intestinal infections, pneumonia, infections involving the lungs, and tuberculosis; that it was an effective treatment for colds, influenza, and pneumonia of children and adult human beings; that it was a preventive against canine distemper, which could be used to produce an immunity against that disease; and that it would aid appetite, digestion, and assimilation. The article would not fulfill the promises of benefit claimed, and it was not effective for the purposes stated and implied.

Delcreo soluble sulfur compound capsules. Misbranding, Section 502 (a), certain statements on the label of the article and in an accompanying circular entitled "Delcreo Soluble Sulfur Compounds" were false and misleading. The statements represented and suggested that the article was effective as a tonic alterative, germicide, disinfectant, and insecticide; that it was an effective treatment for skin diseases, rheumatism, gout, arthritis, and eczema; and that it would heal sores, abrasions, long-standing ulcers, bedsores "and the like." The article would not fulfill the promises of benefit claimed, and it was not effective for the purposes stated and implied. In addition, the statements on the label and in the circular exaggerated the value of sulfur and sulfur compounds since sulfur and sulfur compounds have a very limited usefulness in medicine and veterinary medicine.

DISPOSITION: August 15, 1951. Default decrees of condemnation and destruction.

3577. Misbranding of rubber prophylactics. U. S. v. 2 Vending Machines * * *. (F. D. C. Nos. 31228, 31229. Sample Nos. 31682-L, 31683-L.)

LIBEL FILED: July 6, 1951, Southern District of Illinois.

ALLEGED SHIPMENT: On or about March 1, 12, 14, and 15, 1951, a number of *rubber prophylactics* were shipped from East Newark, N. J., to Chicago, Ill.

PRODUCT: 2 vending machines, each machine containing an unknown number of *rubber prophylactics* at Springfield, Ill.

RESULTS OF INVESTIGATION: The vending machines were serviced and labeled by Paul Paradise, owner of National Sanitary Sales, Chicago, Ill.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing on the machines containing the article, namely, "Protex prophylactics are manufactured under the supervision of the Federal Pure Food and Drug Administration" was false and misleading since the prophylactics had not been manufactured under the supervision of the Federal Food and Drug Administration. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1951. Default decree of condemnation and destruction.

3578 Misbranding of Exercycle device. U. S. v. 5 Devices, etc. (F. D. C. No. 28036. Sample Nos. 46689–K, 46695–K.)

LIBEL FILED: October 7, 1949, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 14 and September 22, 1949, the devices were shipped in the name of the Exercycle Corp. of New York, from Hartford, Conn., to Pittsburgh, Pa.; and on or about June 30, 1949, the Exercycle Corp. of New York shipped from New York, N. Y., 200 copies of a large post card entitled "Now you can Rent an Exercycle."

PRODUCT: 5 *Exercycle* devices at Pittsburgh, Pa., in the possession of the Exercycle Co. of Pittsburgh, together with 200 large post cards and 200 small post cards. Both sizes of post cards were entitled "Now you can Rent an Exercycle." The Exercycle Co. of Pittsburgh caused 200 copies of the small post cards to be printed locally.

Examination showed that the *Exercycle* was a device resembling a wheelless bicycle, operated by an electric motor to produce motion of the pedals, seat, and handle bars.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the large and small post cards accompanying the device were false and misleading since the device was not effective to accomplish the results stated and implied: "* * * To help reduce waist – hips – thighs and look years younger! Helps reduce waistline makes chest expansion more complete * * * aids in relief of muscle soreness helps correct common form of constipation improves circulation * * * improves posture * * * helps reduce hips, thighs, buttocks * * * Exercycle is the easy way to help take off pounds and streamline the figure so that it looks right in today's fashions * * * After normal weight is reached, Exercycle helps keep you slender * * * Excellent for helping correct constipation caused by sedentary habits. * * * helps strengthen abdominal muscles * * * helps strengthen back muscles * * *."

The device was alleged to be misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce.

DISPOSITION: November 9, 1951. The Exercycle Co. of Pittsburgh, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR A LABEL CONTAINING AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS*

3579. Misbranding of cortisone. U. S. v. 99 Vials * * *. (F. D. C. No. 30911. Sample No. 816–L.)

LIBEL FILED: April 10, 1951, Southern District of Florida; amended libel filed May 16, 1951.

ALLEGED SHIPMENT: On or about March 21, 1951, by Supramar Chemicals, Inc., from New York, N. Y.

PRODUCT: 99 unlabeled 20-cc. vials of *cortisone* at Miami, Fla., en route to Buenos Aires, Argentina.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

DISPOSITION: August 16, 1951. Supramar Chemicals, Inc., claimant, having admitted the allegations of the libel for purposes of the instant case, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUG ACTIONABLE BECAUSE OF FAILURE TO BEAR LABELING INFORMATION LIKELY TO BE READ AND UNDERSTOOD BY ORDINARY INDIVIDUAL UNDER CUSTOMARY CONDITIONS OF PURCHASE AND USE

3580. Misbranding of Mynex tablets. U. S. v. 82 Boxes * * *. (F. D. C. No. 31403. Sample No. 18141–L.)

LIBEL FILED: August 3, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about May 2, 1951, by Marlene's, Inc., from Chicago, Ill.

PRODUCT: 82 63-tablet boxes of *Mynex tablets* at Phoenix, Ariz. Analysis showed that the product contained substantially less than the declared amount of vitamin D.

LABEL, IN PART: "A Dietary Supplement * * * Mynex * * * Each Maroon Tablet Contains: * * * Vitamin D 200 Int. units."

NATURE OF CHARGE: Misbranding, Section 502 (c), the information required by Section 502 (a) to appear on the label of the article, namely, a statement that *Mynex tablets* would not make one reduce, was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices, on the label) and in such terms as to render such statement likely to be read and understood by the ordinary individual under customary conditions of purchase and use since such statement appeared inside the cellophane wrapped box; and in the light of the representations made and suggested for the article, under conditions of use as are customary and usual, such statement should appear upon the immediate container of the article.

*See also Nos. 3554–3564.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: September 26, 1951. Default decree of condemnation and destruction.

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PRODUCTS

[1] (3550) Injunction issued. Contains opinions of the court.
[2] (3553) Injunction issued.
[3] (3567) Seizure contested. Contains opinion of the court.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3550) Injunction issued. Contains opinions of the court.
[2] (3553) Injunction issued.
[3] (3567) Seizure contested. Contains opinion of the court.

[1] (3550) Injunction issued. Contains opinions of the court.
[2] (3553) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3581–3600

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 28, 1952.*

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*For omission of, or unsatisfactory, ingredients statements, see No. 3584; imitation of, and sale under name of, another drug, No. 3584; failure to bear a label containing an accurate statement of the quantity of the contents, No. 3584; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3584.

991920—52——1

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3581. Misbranding of Special Formula capsules. U. S. v. 1 Drum * * *. (F. D. C. No. 31191. Sample No. 21432–L.)

LIBEL FILED: June 12, 1951, Northern District of Alabama.

ALLEGED SHIPMENT: On or about April 30, 1951, by the Rowell Laboratories, from Baudette, Minn.

PRODUCT: 1 5,000-capsule drum of *Special Formula capsules* at Ashland, Ala., in possession of the J. Q. Adams Drug Co.

Analysis showed that the product contained approximately 8 grains of arsenic trioxide per capsule.

RESULTS OF INVESTIGATION: The J. Q. Adams Drug Co. repackaged and relabeled a portion of the contents of the drum into boxes. At the time of seizure there were approximately 4,250 capsules in the drum, 53 boxes of the repackaged product, and a supply of empty boxes in the possession of the above company.

LABEL, IN PART: (Drum) "5000 Capsules Special Formula Each Capsule contains Ingredients Arsenous Acid * * * (Arsenic Trioxide) 10 grains Caution: To be used only on or by the prescription of a physician or veterinarian. * * *"; (repackaged product, box) "Wonder Mange Capsules (canine) * * * Each capsule contains 10 grains Sodium 2 Arsenious Acid * * *."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling, namely (box label), "One capsule every 3 days until symptoms disappear"; and, Section 502 (a), the statement on the box label "Mange Capsules (canine) These capsules may be used in the treatment of all types of Mange on dogs" was false and misleading since the article was not effective in the treatment of mange on dogs, and the statement also on the box label "Sodium 2 Arsenious Acid" was false and misleading since the article contained no sodium compound. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the capsules in the drum failed to bear adequate directions for use. The article was misbranded in the above respect when introduced into and while in interstate commerce.

DISPOSITION: July 24, 1951. Default decree of condemnation and destruction.

3582. Misbranding of Hydr-Oxy-Colon device. U. S. v. 1 Device, etc. (F. D. C. No. 31736. Sample No. 21292–L.)

LIBEL FILED: October 3, 1951, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about July 16 and 21, 1951, by the United X-Ray & Equipment Co., from Los Angeles, Calif., and Dallas, Tex.

PRODUCT: 1 *Hydr-Oxy-Colon device* at Natchez, Miss., together with a 12-page booklet entitled "Dewelles Detoxacolon Oxygen Therapy," a 2-page treatment chart headed "Pathology Location Appearance Treatment," copy for use in preparing newspaper advertising entitled "Something New Has Been Added." and copy for preparing postal cards entitled "Free To You."

The device was designed for the administration of mixed oxygen and water as an enema.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying printed matter described above were false and misleading. The statements and designs represented and suggested that the device was an adequate and effective treatment for asthma, diabetes, arthritis, high blood pressure, low blood pressure, kidney disorders, neuritis, colitis, prolapse of the rectum and sigmoid, spastic colitis, ulcerative colitis, ptosis of the colon, spasticity of the rectum, extreme ulceration of the lower bowel, common cold, sinusitis, dysentery, flaccid condition of the sphincters, amebic dysentery, heart conditions, hay fever, acute coryza, anemia, epilepsy, toxemias of pregnancy, and infections and inflammations of the female reproductive organs; that the device was an excellent treatment following childbirth to return muscle tone; that it would eliminate distress and disease; and that it would correct chronic ailments or pathological changes and bring about a restoration of health. The device was not an adequate and effective treatment for such disease conditions, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (j), the article was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling since in the post partum period and in the acute stages of vaginal infections, treatment as directed would force infective material into or through the cervical canal, resulting in ascending infection with probable serious consequences to the health of the patient.

The device was misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: November 20, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3583. Misbranding of C. M. A. Formula B.–88, C. M. A. Formula K & B 55, Hancock's Formula No. 4, C. M. A. Formula S.–99, C. M. A. Formula S.L.–22, C. M. A. Old Style Indian Herb Medicine #10, and sugar tablets, and refusal to permit inspection. U. S. v. Coordinative Medicines Assn., Inc. (C. M. A., Hancock Medicine Co., and Christian Mutual Assn.), and Robert E. Davis and Carrie Davis. Pleas of not guilty. Tried to the court. Verdict of guilty. Corporation fined $800, Robert E. Davis, $1,000, and Carrie Davis, $400. Robert E. Davis and Carrie Davis each sentenced to 2 years in prison; prison sentences suspended and each individual defendant placed on probation for 3 years. (F. D. C. No. 30027. Sample Nos. 51990–K, 51992–K, 54535–K, 54536–K, 54542–K to 54545–K, incl.)

INFORMATION FILED: February 9, 1951, Southern District of Indiana, against Coordinative Medicines Assn., Inc., Indianapolis, Ind., also trading under the names of C. M. A., Hancock Medicine Co., and Christian Mutual Assn., and against Robert E. Davis, president, and Carrie Davis, secretary-treasurer of the corporation.

ALLEGED VIOLATION: Between November 1949 and on or about March 2, 1950, the defendants caused to be introduced into interstate commerce at Indianapolis, Ind., for delivery into the States of Ohio, Mississippi, and Alabama,

*See also No. 3581 (human and veterinary use).

quantities of *C. M. A. Formula B.–88, C. M. A. Formula K & B 55, Hancock's Formula No. 4, C. M. A. Formula S.–99, C. M. A. Formula S. L.–22, C. M. A. Old Style Indian Herb Medicine #10*, and a number of unnamed tablets which consisted essentially of sugar.

On or about October 10 and 27, 1949, Robert E. Davis, president of the corporation and the operator and custodian of its factory at Indianapolis, Ind., refused entry and inspection of the corporation's factory upon the request of an employee of the Food and Drug Administration made at a reasonable time and in accordance with the provisions of Section 704 of the Act.

LABEL, IN PART: "C. M. A. Formula B.–88 Contains: Blue Flag Root, Burdock, Red Clover, Yellow Dock, Sarsaparilla, Wild Ginger"; "C. M. A. Formula K & B 55 Contains: Buchu, Parsley Piert, Wild Carrot, Uva Ursa, Juniper Berries and other inactive ingredients"; "Hancock's Formula No. 4 * * * Ingredients Tincture Guaiac, Spirit Lavender, Sweet Spirit Niter, Balsam Copaiba"; "C. M. A. Formula S.–99 Contains: Cubebs, Stillingia, White Pond Lilly, Turkey Corn, Plantain, Malva, Angelica, Yellow Dock and Sarsaparilla"; "C. M. A. Formula S. L.–22 Contains: Goldenseal, Mandrake, Gentian Angelica"; and "C. M. A. Old Style Indian Herb Medicine #10 * * * Contains: Senna, Cascara sagrada, uva ursa, juniper, doggrass, licorice, fennel, anis, elder flowers and coriander."

NATURE OF CHARGE: *C. M. A. Formula B.–88, C. M. A. Formula S.–99*, and *sugar tablets*. Misbranding, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use since the directions for use in the labeling did not state the purposes or conditions for which the drugs were intended to be used.

C. M. A. Formula K & B 55. Misbranding, Section 502 (a), certain statements in an accompanying folder entitled "Coordinative Medicines Assn. Inc." which represented and suggested that the article would be efficacious in the treatment of diseases of the kidneys and bladder and other diseases of the genito-urinary organs were false and misleading since the article would not be efficacious in the treatment of such diseases.

Hancock's Formula No. 4. Misbranding, Section 502 (a), the label statement "Recommended in cases of Infection Of The Genito-Urinary Tract" was false and misleading since the article would not be efficacious in the treatment of infections of the genito-urinary tract.

C. M. A. Formula S. L.–22. Misbranding, Section 502 (a), the statement "This is used in cases of stomach disorders but where the use of a laxative is not so pronounced" appearing in an accompanying folder entitled "Coordinative Medicines Assn. Inc., Tampa Florida" was false and misleading since the article would not be efficacious in the treatment of stomach disorders whether or not a laxative was indicated.

C. M. A. Old Style Indian Herb Medicine #10. Misbranding, Section 502 (a), certain statements in an accompanying folder entitled "Coordinative Medicines Association, Inc., Tampa, Florida" were false and misleading. The statements represented and suggested that the article would be efficacious to purify the blood and aid nature in the elimination of poisons; that it would be efficacious to enable the stomach, liver, and kidneys to function properly; and that it would prevent and benefit irritation of the bladder, short-windedness, and a dull feeling in the chest which sometimes affects the heart. The article would not be efficacious for the purposes represented.

The information charged also that another article known as *C. M. A. Formula #21 tablets* was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: July 20, 1951. Pleas of not guilty having been entered, the case came on for trial before the court without a jury on July 16, 1951. At the conclusion of the trial on July 20, 1951, the court rendered a verdict of guilty on all counts and fined the corporation $800, Robert E. Davis $1,000, and Carrie Davis $400. In addition, Robert E. Davis and Carrie Davis were each sentenced to 2 years in prison. The prison sentences were suspended, however, and each individual defendant was placed on probation for 3 years, conditioned that each would not violate Federal or State food and drug laws or the State Medical Practices Act.

3584. Adulteration and misbranding of dextro-amphetamine sulfate tablets. U. S. v. 5 Bottles * * *. (F. D. C. No. 31381. Sample No. 3111–L.)

LIBEL FILED: July 31, 1951, District of Columbia.

ALLEGED SHIPMENT: On or about April 12, 1951, by the Kumfort Drug Products Co., from Cleveland, Ohio.

PRODUCT: 5 unlabeled bottles each containing 1,000 tablets represented as 5 milligram *dextro-amphetamine sulfate tablets*. Examination showed that each tablet contained approximately 4.25 milligrams of amphetamine sulfate.

RESULTS OF INVESTIGATION: The product was shipped in response to an oral order given by the consignee to a representative of the shipper for 5 milligram *dextro-amphetamine sulfate tablets*.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, namely, 4.25 milligram amphetamine sulfate tablets, had been substituted for 5 milligram *dextro-amphetamine sulfate tablets*.

Misbranding, Section 502 (i) (2), the article was an imitation of another drug; Section 502 (i) (3), it was offered for sale under the name of another drug; Sections 502 (b) (1) and (2), it failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug, namely, amphetamine sulfate tablets; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: August 31, 1951. Default decree of condemnation and destruction.

3585. Misbranding of male hormone with vitamin B_1. U. S. v. 35 Packages, etc. (F. D. C. No. 31383. Sample No. 1214–L.)

LIBEL FILED: On or about August 13, 1951, Northern District of Georgia.

ALLEGED SHIPMENT: On or about October 16 and December 8, 1950, and February 16 and March 8, 1951, by the Hudson Products Co., from Long Beach, Calif.

PRODUCT: 35 30-tablet packages and 19 60-tablet packages of *male hormone with vitamin B_1* at Atlanta, Ga.

LABEL, IN PART: (Package) "Male Hormone (methyl testosterone) combined with Vitamin B_1 * * * Daily recommended intake of one light and one dark (higher potency) tablet provides 5 milligrams of Methyl Testosterone and 3 milligrams of Vitamin B_1 (Thiamin Hydrochloride)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label on the packages of the article contained statements which represented and suggested that when taken as directed, the article would be efficacious in the treatment of male hormone deficiency, which statements were false and misleading since the article when taken as directed, was not efficacious for such purpose; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to state all of the diseases or conditions of the body for which the article was intended; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form, as are necessary for the protection of users since the technical medical terminology in which the cautionary statement on the labeling was couched, namely,

> CAUTION: The male hormone should not be taken by anyone with carcinoma of the prostate or urinary retention probably due to carcinoma of the prostate or by anyone with cardio-vascular disease, defects of spermatogenesis, sterility whether absolute or partial, or debilitation due to disease. Caution should be exercised when taking hormones for long periods since they have been reported as inhibiting spermatogenesis. Take only as directed. Children and young adults must not use except under constant direct supervision of a physician.

was inadequate to warn the ordinary lay user that use of the product may accelerate the malignant growth of the prostate gland or may cause sterility.

DISPOSITION: August 27, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3586. Adulteration of extract of Glycyrrhiza. U. S. v. MacAndrews & Forbes Co. Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 30119. Sample No. 81757–K.)

INFORMATION FILED: April 26, 1951, District of New Jersey, against MacAndrews & Forbes Co., a corporation, Camden, N. J.

ALLEGED SHIPMENT: On or about October 13, 1950, from the State of New Jersey into the State of Tennessee.

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), the article had been prepared under insanitary conditions whereby it may have become contaminated with filth.

The information alleged also that the defendent had shipped in interstate commerce a quantity of licorice paste which was adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 17552.

DISPOSITION: July 11, 1951. A plea of guilty having been entered, the court placed the defendant on probation for 2 years on the count charging adulteration of the *Glycyrrhiza*. (The defendant was fined $250 on the count charging adulteration of licorice paste.)

3587. Adulteration of Lobelia herb. U. S. v. 11 Bales * * *. (F. D. C. No. 30709. Sample No. 10773-L.)

LIBEL FILED: March 19, 1951, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 13, 1950, and January 5, 1951, by the Smoky Mountain Drug Co., from Bristol, Tenn.

PRODUCT: 11 bales, each containing from 81 to 183 pounds, of *Lobelia herb* at Tipton, Ind.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, insect fragments, and rodent hair fragments.

DISPOSITION: June 5, 1951. The Smoky Mountain Drug Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for washing and pasteurizing, under the supervision of the Federal Security Agency. On June 20, 1951, the decree was amended to provide for release of the product for the purpose of extracting the alkaloids therefrom, in lieu of its release for washing and pasteurizing.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3588. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Drum * * * (and 1 other seizure action). (F. D. C. No. 31317. Sample Nos. 10341-L, 10342-L.)

LIBELS FILED: July 3, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 5 and 11, 1951, by Strong Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 1 drum containing 52,400 tablets and 1 drum containing 33,200 tablets of *conjugated estrogens* at Detroit, Mich.

Analysis showed that 1 drum of the product (0.625 mg. tablets) contained a total amount of estrogenic steroids calculated as 0.40 mg. of sodium estrone sulfate per tablet and that the other drum of the product (1.25 mg. tablets) contained a total amount of estrogenic steroids calculated as 0.68 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: (Drum) "Contents 52400 * * * Name: Conjugated Estrogenic Hormone Substance * * * (0.625 mg. activity)" and "Contents 33200 * * * Name: Conjugated Estrogenic Hormone Substance Tablets (1.25 mg. activity)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess, namely, 0.625 mg. per tablet and 1.25 mg. per tablet, respectively, of estrogens in their naturally occurring water-soluble conjugated form expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the following statements on the labels of the articles were false and misleading as applied to products which contained less than the stated amounts of total estrogenic steroids calculated as sodium estrone sulfate: "Formula contains at time of manufacture per tablet Estrogens (naturally occurring water-soluble conjugated form) expressed as sodium estrone sulfate 0.625 mg. * * *" and "Formula contains at time of manufacture per tablet Estrogens (naturally occurring water-soluble conjugated form) expressed as sodium estrone sulfate 1.25 mg. * * *."

*See also No. 3584.

DISPOSITION: August 10, 1951. Strong Cobb & Co., Inc., claimant, having consented to the entry of decrees, judgments of condemnation were entered and the court ordered that the products be released under bond for reprocessing to bring them up to the required potency, under the supervision of the Federal Security Administrator.

3589. Adulteration and misbranding of oil of peppermint. U. S. v. 3 Bottles * * *. (F. D. C. No. 31185. Sample Nos. 15265–L, 15353–L.)

LIBEL FILED: On or about June 21, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about May 8 and November 30, 1950, by Berje Chemical Products, Inc., from New York, N. Y.

PRODUCT: 3 bottles of *oil of peppermint* at Kansas City, Mo. Analysis of the product showed that it failed to comply with the requirements of the United States Pharmacopeia and that it also contained mineral oil.

LABEL, IN PART: (Bottle) "Oil Peppermint Redistilled U.S.P. 5 Lbs."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "oil of peppermint," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality and purity fell below, the official standard since the article failed to meet the tests for solubility in alcohol, specific gravity, and optical rotation; and it failed to comply with the assay for total menthol set forth in such compendium. Further adulteration, Section 501 (d) (2), an article containing mineral oil had been substituted for oil of peppermint.

Misbranding, Section 502 (a), the label designation "Oil Peppermint Redistilled U. S. P." was false and misleading as applied to an article which failed to meet the standard set forth in the United States Pharmacopeia for oil of peppermint.

DISPOSITION: August 31, 1951. Default decree of destruction.

3590. Adulteration and misbranding of clinical thermometers. U. S. v. 696 Thermometers * * *. (F. D. C. No. 31707. Sample No. 16776–L.)

LIBEL FILED: September 17, 1951, Southern District of California.

ALLEGED SHIPMENT: On or about July 6, 1951, by the Emrose Thermometer Co., from Bronx, N. Y.

PRODUCT: 696 *clinical thermometers* at Ventura, Calif. Examination of 24 thermometers showed that a total of 8 were defective in one or more respects.

LABEL, IN PART: (Envelope) "Style Oral Emrose 'Medik-Aid' A Superior Clinical Thermometer."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the articles fell below that which they purported and were represented to possess.

Misbranding, Section 502 (a), the statements which appeared in the labeling of the articles, namely, "A Superior Clinical Thermometer," "This certifies that the thermometer * * * has been tested * * * at 98°, 102°, and 106°, F. or its equivalent in centigrade scale and is correct within plus or minus 2/10 F. or C. at any of these test points * * * This test is governed by a standard thermometer which has been tested by the Bureau of Standards, Washington, D. C.," and "Accurate," were false and misleading as applied to articles which failed to meet the stated standard of accuracy, contained trapped gas, failed to repeat readings, were hard shakers, or had markings less than

one-fourth inch from the end of the thermometer, which defects are not normal to clinical thermometers.

DISPOSITION: November 6, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3591. Misbranding of Sacrasol capsules. U. S. v. 43 Bottles, etc. (F. D. C. No. 29100. Sample No. 75706–K.)

LIBEL FILED: May 4, 1950, Southern District of Iowa.

ALLEGED SHIPMENT: On or about March 10, 1950, by Edwin K. Osmun, a member of the firm of Physicians' Ethical Products, from Chicago, Ill.

PRODUCT: 43 100-capsule bottles of *Sacrasol* at Marshalltown, Iowa, together with circulars entitled "Sacrasol In Diabetes Mellitus" and "What Is Sacrasol?" a card entitled "Announcement," and a letter dated March 8, 1950, on the letterhead of Physicians' Ethical Products, which was signed "E. K. Osmun."

LABEL, IN PART: "Sacrasol Active Ingredients Syzygium, Vesicaria, Rhus, Aromatics, Apis Virus, Lithium Benzoate, Phosphoric Acid (Dilute), Uranium Nitricum, 1/1000 Gr. per Cap. Thiamin Hydrochloride * * * Distributed by Physicians' Ethical Products 1746 W. 69th St. Chicago 36."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the above-mentioned circulars, card, and letter, were false and misleading. These statements represented and suggested that the article was an effective treatment for diabetes, itching skin, excessive thirst, and abnormal appetite associated with diabetes; for preventing toxic build-up in the liver or kidneys; for correcting dysfunctions in the carbohydrate metabolism; for disposing of excess sugar in the blood and urine; for diabetic ulcerations; and for weakness, emaciation, enuresis due to atony, hematuria, cystitis, all forms of urinary and kidney difficulties, nephralgia, dropsy, flatulence, diarrhea, periosteal inflammation, abscesses, gangrene, gout, and nettle rash. The article was not an effective treatment for such conditions.

DISPOSITION: On September 22, 1950, Edwin K. Osmun and Charles M. Haft, trading as Physicians' Ethical Products, having filed a motion for the removal of the case to the Northern District of Illinois and an oral argument having been heard in the matter, an order was entered overruling the motion and directing that the case be transferred to the Northern District of Indiana.

On October 15, 1951, the United States District Court for the Northern District of Indiana made an order finding that it had no jurisdiction and remanded the case to the court of original jurisdiction. Thereafter, on November 8, 1951, no one having appeared in the case following its transfer to the Northern District of Indiana or its return to the Southern District of Iowa, a decree was entered by the United States District Court for the Southern District of Iowa, providing for condemnation and destruction of the product.

*See also Nos. 3582, 3583, 3585, 3588–3590.

3592. Misbranding of P. F. Paula Fraser tablets. U. S. v. 33 Cases * * *. (F. D. C. No. 31182. Sample No. 21072–L.)

LIBEL FILED: June 8, 1951, Western District of Texas.

ALLEGED SHIPMENT: In the early part of 1950 and on or about April 25, 1951, from Los Angeles, Calif.

PRODUCT: 33 cases, each containing 144 84-tablet vials, of *P. F. Paula Fraser tablets* at San Antonio, Tex., in the possession of Rowell & Rowell, Inc. Analysis showed that the product consisted essentially of aspirin and calcium glutamate.

RESULTS OF INVESTIGATION: There were in possession of the consignee approximately 30,000 copies of a form letter which were printed locally, and which related to the product.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the form letter were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for pain, swelling, and rigidity of the joints, pains and aches in the muscles, arthritis, neuritis, rheumatism, and lumbago, whereas it was not an adequate and effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 8, 1951. Rowell & Rowell, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3593. Misbranding of Elemin tablets and G & J Formula No. 701 (or 601) tablets. U. S. v. 10 Cases, etc. (F. D. C. No. 31219. Sample Nos. 18868–L, 18869–L.)

LIBEL FILED: June 27, 1951, Northern District of Iowa.

ALLEGED SHIPMENT: On or about March 10, April 17 and 18, and May 3, 1951, by the G & J Distributors, from Berkeley, Calif.

PRODUCT: 10 cases, each containing 12 700-tablet bottles, and 2 cases, each containing 24 120-tablet bottles, of *Elemin tablets*, and 10 cases, each containing 12 350-tablet bottles, and 2 cases, each containing 24 120-tablet bottles, of *G & J Formula No. 701 (or 601) tablets*, at Fort Dodge, Iowa, together with certain accompanying printed matter.

The printed matter consisted of a number of copies of a booklet entitled "Sales Manual, Nutritional Products, Elemin Minerals, G & J Multiple Vitamins"; a book entitled "Health from the Ground Up" by the International Harvester Co.; a booklet entitled "Facts You Should Know," including Senate document No. 264, 74th Congress, Second Session, entitled "Modern Miracle Men" by Rex Beach; a brochure entitled "Soil—A Foundation of Health" published by the International Harvester Co.; a book entitled "The National Malnutrition" by D. T. Quigley, M. D.; and leaflets entitled "Elemin Mineral Tablets," "Its Later Than You Think, Watch Your Diet, Mineralize—Vitaminize," "Composite analysis derived from the reports of the following laboratories," and "The Following is a Reprint of a Published Article for Informative and Educational Purposes Only."

LABEL, IN PART: (Bottles) "Elemin * * * Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a sedimentary mineral deposit, with excipients and color added to sugar coating. Manufactured for Morgen & Bush, Inc. * * * Bakersfield, Calif." and "G & J Formula No. 701 (or 601) Each 2 Tablets Will Supply: Vitamin A (Fish Liver Oils) 5,000 U. S. P. Units Vitamin D (Irradiated Ergosterol) 1,000 U. S. P. Units Vitamin B_1 (Thiamin Hcl and Yeast) 3.0 Mg. Vitamin B_2 (Riboflavin) 2.0 Mg. Vitamin B_6 (Pyridoxine Hcl) 1.0 Mg. Vitamin B_{12} 1.0 Mcg. Vitamin C (Ascorbic Acid) 50.0 Mg. Vitamin E (Mixed Tocopherol) 3.0 Mg. Niacin 20.0 Mg. Calcium Panthothenate 5.0 Mg. Concentrated Beef Liver Extract 65.0 Mg. * * * Mfd. for and Dist. by G & J Distributors * * * Berkeley 4, California."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the printed matter accompanying the articles were false and misleading. The statements represented and suggested that the articles supplied a universal need; that clay, described as "sedimentary mineral deposit" and denominated "panaca," used as an ingredient in the article, "Elemin Tablets," contributed significantly to the diet of the user; that ordinary foods, because of soil depletion and processing, do not supply the need for vitamins and minerals so that supplementation of the usual diet is essential; that ninety-nine percent of the American people are deficient in minerals, resulting in disease, suffering, and shortening of life; that the symptoms, conditions, and diseases that beset the human body most commonly result from dietary deficiencies, and such symptoms, conditions, and diseases could be prevented and adequately treated by the use of *Elemin tablets* and *G & J Formula No. 701 (or 601) tablets*; that the articles would be effective in the prevention and treatment of all sorts of discomfort, soreness, pain and stiffness, all infections, infections of the upper respiratory tract, including colds, grippe, and pneumonia, brain infections, chronic constitutional ailments, diseases of the adenoids, tonsils, digestive organs, lungs, blood vessels, skeleton, and gums, degenerative diseases, venereal diseases, nerve and brain diseases including insanity, stupidity in children, heart diseases including rheumatic heart disease, periodontal diseases, tooth decay, pyorrhea, arthritis, rheumatic fever, tuberculosis, pimples, constipation, neuroses, irritability, chronic gastritis, stomach and duodenal ulcers, stomach cancer, osteomalacia, nephritis, arteriolosclerosis, skeletal weakness, and all ailments and afflictions to which people may become heir; and that consumption of the articles would eliminate 70 to 80 percent of present-day diseases, bring to an end susceptibility to, and afford immunity from, infection, extend the average age to well over 100 years, and result in good health, happiness, and contentment. The articles were not capable of fulfilling the promises of benefit made for them; they were not effective in the prevention and treatment of the symptoms, diseases, and conditions stated and implied; and the impression conveyed by the statements was contrary to fact.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: July 28, 1951. Default decree of condemnation and destruction.

3594. Misbranding of M. F. Co.'s Minerals. U. S. v. 99 Bottles * * *. (F. D. C. No. 31599. Sample No. 11304–L.)

LIBEL FILED: August 7, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 20, 1951, by the Mineral Food Co., from Indianapolis, Ind.

PRODUCT: 99 bottles of *M. F. Co.'s Minerals*, each bottle containing 270 tablets, at New Philadelphia, Ohio, together with a number of accompanying circulars entitled "Mineral Supplement."

LABEL, IN PART: (Bottle) "The M. F. Co.'s Minerals 270 Tablets * * * Contains: Potassium Iodide, Calcium Phosphate, Calcium Carbonate, Sodium Phosphate, Iron Sulfate Exsiccated, Sodium Chloride (iodized salt). Six tablets each day will supply the full daily adult minimum requirements of Calcium, ½ that of Phosphorus, 1½ that of iron, and 2 times that of iodine."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circular were false and misleading. The statements represented and suggested that the article would correct basic unnatural disorders and thereby enable nature to correct illness or disease regardless of the name by which it is known; that it would afford physical wrecks freedom from stubborn suffering and renew their strength; that it would eliminate pain and soreness of years' duration, enabling the sufferer to sleep like a school child; and that it would render the user who needs a mineral supplement 100 percent healthy. The statements were contrary to fact.

DISPOSITION: September 7, 1951. Default decree of condemnation and destruction.

3595. Misbranding of throat lozenges. U. S. v. 135,000 Lozenges, etc. (F. D. C. No. 31139. Sample Nos. 23084–L, 23085–L, 24681–L.)

LIBEL FILED: May 19, 1951, Northern District of New York.

ALLEGED SHIPMENT: On or about January 24 and April 19, 1951, by Strong Cobb & Co., Inc., from Cleveland, Ohio.

PRODUCT: 135,000 *throat lozenges* in 8 drums, 12 display cartons, each containing 24 vials of 14 *throat lozenges* each, and a number of labels at Syracuse, N. Y.

RESULTS OF INVESTIGATION: The lozenges contained in the vials in the display cartons had been repacked by the Approved Pharmaceutical Corp., Syracuse, N. Y., from the drums in which they had been shipped. In addition, the repacker had in its possession certain labels which were intended to be attached to display cartons containing the lozenges.

LABEL, IN PART: (Drum) "Special Lozenges CT Light Orange * * * Formula contains at time of manufacture: per lozenge Tyrothricin 2 mg. Benzocaine 5 mg. Cetyl Dimethyl Benzyl Ammonium Chloride. Directions: For sore throat."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement upon the drum label "For sore throat" was false and misleading since the article was not an effective treatment for sore throat. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the following statements appearing upon the labels attached to the display cartons were false and misleading since the article was not effective for the purposes stated upon the label and implied therein: "* * * Germ Killer * * * Destroys Bacteria * * *

Keeps Out New Germs * * * Faster than Penicillin * * * on gram-positive germs such as: diphtheria bacilli-streptococci-pneumococci and other bacteria causing common sore throat * * *." The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: Decree entered September 29, 1951; amended decree entered October 9, 1951. The Approved Pharmaceutical Corp., claimant, consented to the entry of these decrees, which provided that the labels and display cartons be destroyed; that the portion of the labels on the 8 drums of the product containing the words "For sore throat" be obliterated; and that the lozenges be released to the claimant under bond for repackaging and relabeling.

3596. Misbranding of Muscle-Rub. U. S. v. 33 Bottles, etc. (F. D. C. No. 31209. Sample No. 15783–L.)

LIBEL FILED: On or about June 22, 1951, District of Kansas.

ALLEGED SHIPMENT: On or about January 2, 1951, by Muscle Rub Distributors, from Los Angeles, Calif.

PRODUCT: 33 6-ounce bottles and 12 12-ounce bottles of *Muscle-Rub* at Newton, Kans., together with accompanying leaflets entitled "Muscle-Rub," and accompanying placards, a window streamer, and a display sheet, all entitled "Prove Free."

LABEL, IN PART: "Muscle-Rub Contains Isopropyl Alcohol 75% Ethyl Alcohol 1.8% Methyl Salicylate, Camphor, Menthol & Fld. Witch Hazel."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and on the accompanying leaflets, placards, window streamer, and display sheet were false and misleading. The statements and designs represented and suggested that the article was an adequate and effective treatment for arthritis, rheumatism, neuralgia, sciatica, neuritis, lumbago, swollen, aching joints, soreness of muscles, sprains, and bruises. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: September 6, 1951. Default decree of condemnation and destruction.

3597. Misbranding of Jessamine's Electro-Way device. U. S. v. 5 Devices, etc. (F. D. C. No. 31320. Sample No. 13480–L.)

LIBEL FILED: July 10, 1951, District of Utah.

ALLEGED SHIPMENT: During May 1950, by Jessamine's Electro-Way Slenderizing Salons, Oakland, Calif.

PRODUCT: 5 *Jessamine's Electro-Way devices* at Salt Lake City, Utah, together with a number of leaflets entitled "Reducing Made Easy." The device consisted of two different models; one model was known as "Salonette" and the other model as "Electro-Vac." The device was designed to reduce the 110-volt household electrical current to a lower voltage.

It was accompanied by pads which could be attached to the device by means of which electricity was applied to various parts of the body. The labeling contained the following directions: "Soak pads thoroughly in warm or hot water. Connect pads to the cords in pairs and strap onto the spots to be treated. Lie down and relax."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying leaflets were false and misleading. The statements represented and suggested that the device was effective in bringing about a reduction in

weight, improving health and figure, in development of the breast, removal of wrinkles, correction of sagging muscles, muscle toning and exercising, promoting the growth of hair, and in relief of nerve and muscle tension, arthritis, varicose veins, high blood pressure, paralysis, constipation, psoriasis, headache, menstrual cramps, aches and pains, sinus, shingles, and cramps; and that the device was effective to improve the circulation of the blood. The device was not effective for the purposes represented.

DISPOSITION: October 19, 1951. Default decree of condemnation. The court ordered that the devices be turned over to the United States marshal for disposition. On October 25, 1951, an amended order was entered which directed that the United States marshal deliver the devices to the Food and Drug Administration.

DRUGS FOR VETERINARY USE*

3598. Misbranding of Agricultural College Formula. U. S. v. 14 Packages, etc. (F. D. C. No. 31409. Sample No. 1706–L.)

LIBEL FILED: July 31, 1951, Northern District of Georgia.

ALLEGED SHIPMENT: On or about April 24, 1951, by Whitmoyer Laboratories, Inc., from Myerstown, Pa.

PRODUCT: 14 50-pound packages and 14 25-pound packages of *Agricultural College Formula* at Gainesville, Ga.

LABEL, IN PART: "Agricultural College Formula * * * Ingredients Powdered Zinc Sulphate, Powdered Sodium Sulphocarbolate (Phenolsulphonate), Powdered Quebracho Ext., Vitamin B_{12} Feed Supplement, Dried Brewers' Yeast, Gentian, Nux Vomica 2.08% (contains 1.15% Strychnine), Anise."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not effective in combating bacterial and protozoan infections and nonspecific types of enteritis of poultry: "Agricultural College Formula is useful for combating bacterial and protozoan infections of the intestinal tract when used in conjunction with certain other drugs in accordance with recommendations of veterinarians and poultry pathologists * * * For Non-Specific Types of Enteritis."

DISPOSITION: September 25, 1951. Whitmoyer Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Food and Drug Administration.

3599. Misbranding of Poultry Sacodine Liquid. U. S. v. 15 Bottles * * *. (F. D. C. No. 31611. Sample No. 34900–L.)

LIBEL FILED: August 10, 1951, Northern District of Iowa.

ALLEGED SHIPMENT: On or about February 28 and June 18, 1951, by Fidelity Laboratories, Inc., from Chicago, Ill.

PRODUCT: 15 1-quart bottles of *Poultry Sacodine Liquid* at Sioux City, Iowa.

LABEL, IN PART: "Rx Fidelity Laboratories, Inc. Poultry Sacodine Liquid Ingredients Copper sulphate ..... 10.31% Zinc sulphate ..... 1.70% Formaldehyde solution ..... 4.01% Hydrochloric Acid solution ..... 1.22% Proflavine hydrochloride."

*See also No. 3581.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "As an aid in preventing infection in chickens and turkeys * * * As an aid in overcoming an infection * * * An inhibitor for certain bacteria and molds" were false and misleading since the article was not an effective preventive and treatment for infections caused by bacteria and molds in chickens and turkeys.

DISPOSITION: September 11, 1951. Default decree of condemnation and destruction.

3600. Misbranding of Gaysal, Guysol, and Alkanite. U. S. v. 41 Bottles, etc. (F. D. C. No. 31205. Sample Nos. 19239–L, 19240–L, 19258–L.)

LIBEL FILED: June 22, 1951, District of Minnesota.

ALLEGED SHIPMENT: On or about April 29, 1950, and February 7 and May 8 and 9, 1951, by the Peerless Serum Co., from Kansas City, Mo.

PRODUCT: 41 1-pint bottles of *Gaysal*, 33 1-pint bottles of *Guysol*, and 70 1-pound bottles of *Alkanite* at St. Paul, Minn., together with a number of accompanying booklets entitled "Peerless March, 1951 Price List."

LABEL, IN PART: (Bottle) "Gaysal * * * Active Ingredients Potassium Guaiacolsulfonate Sodium Sulphocarbolate Ammonium Chloride," "Guysol Each ounce Contains Creosote Guaiacol Liquid Oil Eucalyptus Cresylic Acid Gum Camphor Emulsifying Base," and "Alkanite * * * Contains Sodium Hydroxide, 80% Contains: Sodium Hydroxide Copper Suluhate [sic] Sodium Hyposulphite Potassium Guaiacolsulfonate Sodium Bicarbonate Salt Phenolphthalein Oil Anise Colored."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements which appeared in the labeling of the articles were false and misleading since the articles were not effective in the treatment of the conditions stated and implied: (*Gaysal*, bottle label) "Suggested as an aid in some of the common inflammatory respiratory disorders" and (*Gaysal*, booklet) "Bronchopneumonia * * * Gaysal * * * Influenza in swine * * * Gaysal * * * as an aid in the internal treatment of swine suffering from common inflammatory respiratory disorders"; (*Guysol*, booklet) "Bronchopneumonia * * * Guysol * * * influenza in swine * * * Guysol * * * suggested as an aid in the internal treatment of swine and poultry suffering from common inflammatory respiratory disorders"; and (*Alkanite*, booklet) "Enteritis in swine * * * Alkanite is suggested in the alkaline treatment of swine suffering from various types of enteric troubles. It aids in relieving systemic acidosis which usually accompanies intestinal pathology."

DISPOSITION: August 10, 1951. Default decree of destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3581 TO 3600

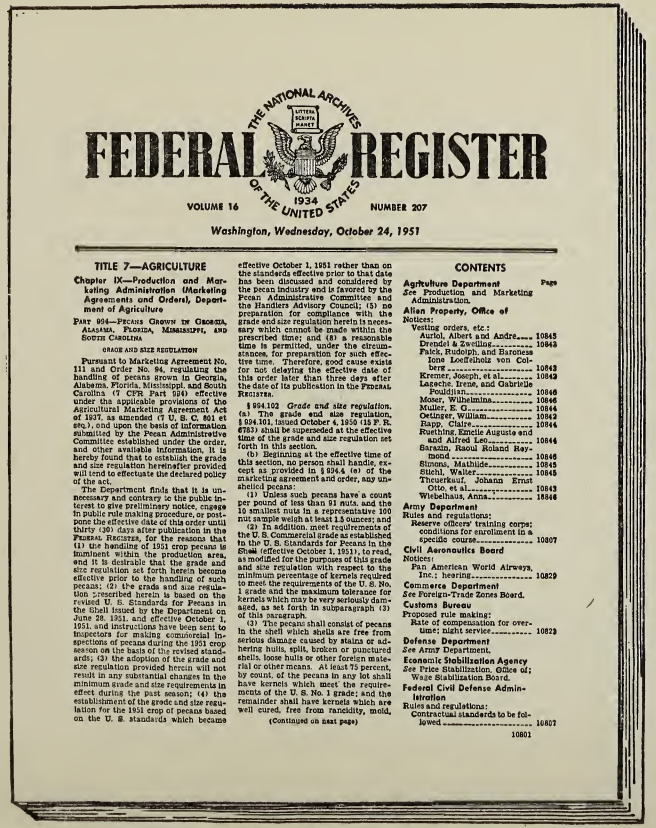
PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3583) Prosecution contested.

[1] (3583) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1952



THE NATIONAL ARCHIVES
LIBERTY INSURES LIBERTY

FEDERAL REGISTER

1934 OF THE UNITED STATES

VOLUME 16 NUMBER 207

Washington, Wednesday, October 24, 1951

TITLE 7—AGRICULTURE

Chapter IX—Production and Marketing Administration (Marketing Agreements and Orders), Department of Agriculture

PART 994—PECANS GROWN IN GEORGIA, ALABAMA, FLORIDA, MISSISSIPPI, AND SOUTH CAROLINA

GRADE AND SIZE REGULATION

Pursuant to Marketing Agreement No. 111 and Order No. 94, regulating the handling of pecans grown in Georgia, Alabama, Florida, Mississippi, and South Carolina (7 CFR, Part 994) effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and upon the basis of information submitted by the Pecan Administrative Committee established under the order, and other available information, it is hereby found that to establish the grade and size regulation hereinafter provided will tend to effectuate the declared policy of the act.

The Department finds that it is unnecessary and contrary to the public interest to give preliminary notice, engage in public rule making procedure, or postpone the effective date of this order until thirty (30) days after publication in the FEDERAL REGISTER, for the reasons that (1) the handling of 1951 crop pecans is imminent within the production area, and it is desirable that the grade and size regulation set forth herein become effective prior to the handling of such pecans; (2) the grade and size regulation prescribed herein is based on the revised U. S. Standards for Pecans in the Shell issued by the Department on June 28, 1951, and effective October 1, 1951, and instructions have been sent to inspectors for making commercial inspections of pecans during the 1951 crop season on the basis of the revised standards; (3) the adoption of the grade and size regulation provided herein will not result in any substantial changes in the minimum grade and size requirements in effect during the past season; (4) the establishment of the grade and size regulation for the 1951 crop of pecans based on the U. S. standards which became effective October 1, 1951 rather than on the standards effective prior to that date has been discussed and considered by the pecan industry and is favored by the Pecan Administrative Committee and the Handlers Advisory Council; (5) no preparation for compliance with the grade and size regulation herein is necessary which cannot be made within the prescribed time; and (6) a reasonable time is permitted, under the circumstances, for preparation for such effective time. Therefore, good cause exists for not delaying the effective date of this order later than three days after the date of its publication in the FEDERAL REGISTER.

§ 994.102 *Grade and size regulation.* (a) The grade and size regulation, § 994.101, issued October 4, 1950 (15 F. R. 6783) shall be superseded at the effective time of the grade and size regulation set forth in this section.

(b) Beginning at the effective time of this section, no person shall handle, except as provided in § 994.4 (e) of the marketing agreement and order, any unshelled pecans:

(1) Unless such pecans have a count per pound of less than 91 nuts, and the 10 smallest nuts in a representative 100 nut sample weigh at least 1.3 ounces; and

(2) In addition, meet requirements of the U. S. Commercial Grade as established in the U. S. Standards for Pecans in the Shell (effective October 1, 1951), to read, as modified for the purposes of this grade and size regulation with respect to the maximum percentage of kernels required to meet the requirements of the U. S. No. 1 grade and the maximum tolerance for kernels which may be very seriously damaged, as set forth in subparagraph (3) of this paragraph.

(3) The pecans shall consist of pecans in the shell which shells are free from serious damage caused by stains or adhering hulls, split, broken or punctured shells, loose hulls or other foreign material or other means. At least 75 percent, by count, of the pecans in any lot shall have kernels which meet the requirements of the U. S. No. 1 grade; and the remainder shall have kernels which are well cured, free from rancidity, mold,

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3601–3620

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *April 11, 1952.*

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994068—52

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3601. Action to enjoin and restrain the interstate shipment of methyltestosterone tablets. U. S. v. Cecil S. Goldberg (Abbey Products Co.). Consent decree granting injunction. (Inj. No. 238.)

COMPLAINT FILED: October 23, 1951, Southern District of California, against Cecil S. Goldberg, trading as the Abbey Products Co., Los Angeles, Calif.

NATURE OF CHARGE: The defendant was engaged in introducing and delivering for introduction into interstate commerce quantities of *methyltestosterone tablets* labeled as "Abbeyettes—Brand of Crystalline Methyltestosterone U. S. P. Each tablet contains 2.5 mg. Methyltestosterone."

The tablets were alleged to be misbranded under Section 502 (a), in that the labeling of the tablets was false and misleading. The labeling represented, implied, and suggested that the tablets were efficacious for the relief of certain symptoms and disease conditions, namely, nervousness, lack of pep, sleeplessness, vague aches and pains, lack of endurance, and lack of vigor, and that such symptoms and conditions in adult males are due to male hormone deficiency. The tablets were not efficacious for the relief of such symptoms and conditions, and such symptoms and conditions are not due to hormone deficiency in male adults.

The tablets were alleged to be misbranded further under Section 502 (f) (1), in that the labeling did not bear adequate directions for use since adequate directions for use for such tablets by a layman for self-medication cannot be prepared because the existence of a hormone deficiency can be determined only by a physician; and the tablets were inherently dangerous and not safe and efficacious for use except under the supervision of a physician.

Further misbranding, Section 502 (f) (2), the labeling of the tablets failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form, as are necessary for the protection of the users since the labeling failed to state that the presence of cancer of the prostate can be detected only by a physician; since it failed to state the symptoms of defects of spermatogenesis; and since it failed to bear warnings against unsafe duration of dosage in that it warned against continued use of the drug extending over more than six months, whereas continued use of the tablets in the dosage suggested in the labeling may inhibit spermatogenesis and cause sterility within a period of six months.

Further misbranding, Section 502 (j), the tablets were dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in the labeling since such use of the tablets may result in sterility and may accelerate the malignant growth of a cancer of the prostate gland. The portion of the labeling setting forth the dosage and the frequency of use of the tablets was as follows: "Suggested Dosage: For adult males only: 2 tablets twice each day before breakfast and upon retiring * * * Caution: Do not take more than the dosage recommended. Continued use extending over six months is to be avoided."

DISPOSITION: October 23, 1951. The defendant having consented to the entry of a decree, the court issued an order permanently enjoining the defendant from directly or indirectly introducing or delivering for introduction into interstate commerce any male hormone drug, including testosterone, misbranded under Sections 502 (a), 502 (f) (1) and (2), and 502 (j).

3602. Misbranding of Wonder salve. U. S. v. 22 Jars, etc. (F. D. C. No. 30969. Sample Nos. 11097–L, 11098–L.)

LIBEL FILED: June 29, 1951, Western District of Kentucky.

ALLEGED SHIPMENT: On or about February 9 and 28, 1951, by the Brookgate Remedies Co., from Evansville, Ind.

PRODUCT: 22 2-ounce jars and 7 12-ounce jars of *Wonder salve* at Owensboro, Ky. Examination showed that the product consisted of phenols, including not less than 3.9 percent of carbolic acid, camphor and turpentine oil in an ointment base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "For Use In Treatment of * * * Bruises, Inflammations, and Infections * * * so compounded as to be absolutely harmless unless the user is allergic to one of the * * * ingredients" were false and misleading since the article was not absolutely harmless and was not an adequate and effective treatment for bruises, inflammations, and infections; and, Section 502 (j), the article was dangerous to health when used as recommended in the labeling, namely, "Apply Salve Generously to Affected Parts and Bandage."

DISPOSITION: August 30, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3603. Misbranding of pentobarbital sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. John H. Drake and William H. Childers. Pleas of guilty. Sentence of 12 months and fine of $500 against William H. Childers; execution of sentence suspended and defendant placed on probation for 3 years. John H. Drake fined $150 and placed on probation for 2 years. (F. D. C. No. 30620. Sample Nos. 82196–K, 93245–K, 93251–K, 93254–K.)

INFORMATION FILED: September 5, 1951, Northern District of Georgia, against John H. Drake, manager of Drake's Pharmacy, East Point, Ga., and against William H. Childers, a pharmacist employed in the store.

INTERSTATE SHIPMENT: From the States of Illinois and Pennsylvania into the State of Georgia, of quantities of *pentobarbital sodium capsules* and *dextro-amphetamine sulfate tablets*.

ALLEGED VIOLATION: On or about November 2, 13, 17, and 22, 1950, while the drugs were being held for sale at Drake's Pharmacy after shipment in interstate commerce, quantities of the drugs were repacked and dispensed without a physician's prescription.

William H. Childers in 3 counts of the information and John H. Drake in 1 count were charged with causing the acts of repacking and dispensing the repackaged drugs.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

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*See also No. 3601.

Further misbranding, Section 502 (b) (1), the repackaged *pentobarbital sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor. Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *pentobarbital sodium capsules* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the label of the repackaged *dextro-amphetamine sulfate tablets* failed to bear the common or usual name of the drug.

DISPOSITION: October 19, 1951. Pleas of guilty having been entered, the Court imposed a sentence of 12 months and a fine of $500 against William H. Childers, but suspended the execution of the sentence and placed him on probation for 3 years; and, in addition, the court imposed a fine of $150 against John H. Drake and placed him on probation for 2 years.

3604. Misbranding of pentobarbital sodium capsules. U. S. v. James R. Dupuy. Plea of guilty. Fine of $500 and sentence of 4 months in prison. (F. D. C. No. 31266. Sample Nos. 31080–L to 31082–L, incl.)

INFORMATION FILED: October 17, 1951, Western District of Tennessee, against James R. Dupuy, Memphis, Tenn.

INTERSTATE SHIPMENT: From the State of Missouri into the State of Tennessee, of quantities of *pentobarbital sodium capsules.*

ALLEGED VIOLATION: On or about March 31 and May 10 and 16, 1951, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of the *pentobarbital sodium capsules* to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label containing the name and address of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming, and the repackaged drug failed to bear a label containing the name, and quantity or proportion of such derivative and a juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: October 22, 1951. A plea of guilty having been entered, the court imposed a fine of $500 and a sentence of 4 months in prison.

3605. Adulteration and misbranding of elixir Dall-Phen. U. S. v. 21 Cartons * * *. (F. D. C. No. 31627. Sample Nos. 24625–L, 24632–L.)

LIBEL FILED: August 13, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about April 27, 1951, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: 21 cartons, each containing 12 unlabeled bottles, of *elixir Dall-Phen* at Lincoln Park, N. J. Analysis showed that the product contained not more than 0.1 mg., if any, of thiamine hydrochloride in each 5 cc.

LABEL, IN PART: (Cartons) "1 Pint Elixir Dall-Phen Each teaspoonful (5 cc) contains: Phenobarbital ¼ gr. * * * Thiamine Hydrochloride 2.5 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, "Each teaspoonful (5 cc) contains: * * * Thiamine Hydrochloride 2.5 mg." Misbranding, Section 502 (a), the label statement "Each teaspoonful (5 cc) contains: * * * Thiamine Hydrochloride 2.5 mg." was false and misleading. The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

Further misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and address of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents. Further misbranding, Section 502 (d), the article contained phenobarbital, a derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and its label failed to bear the name and proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in the above respects when introduced into and while in interstate commerce.

DISPOSITION: October 2, 1951. Default decree of condemnation and destruction.

3606. Misbranding of syrup Desoxicol. U. S. v. 214 Bottles, etc. (F. D. C. No. 31603. Sample No. 23452–L.)

LIBEL FILED: August 6, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about March 15 and May 31, 1951, by Brewer & Co., Inc., from Worcester, Mass.

PRODUCT: 214 1-pint bottles and 92 1-gallon bottles of *syrup Desoxicol* at Nutley, N. J.

LABEL, IN PART: "Syrup Desoxicol Alcohol 4 Per Cent Each Fluid Ounce Contains: Chloroform 2 grs. Desoxyephedrine Hydrochloride 8 mg. Potassium Guaiacolsulfonate 12 grs. Sodium Citrate 24 grs. Dosage: As directed by the physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to reveal the purposes and conditions for which the article was to be taken.

DISPOSITION: September 14, 1951. Frankay Laboratories, Inc., Nutley, N. J., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the product be released under bond to be relabeled by affixing to it labels reading "Caution: To be dispensed only by or on the prescription of a physician," and that the relabeling be done under the supervision of the Federal Security Agency.

3607. Misbranding of Hope mineral tablets. U. S. v. 5 Gross Bottles, etc. (F. D. C. No. 31620. Sample No. 13685–L.)

LIBEL FILED: On or about August 20, 1951, District of Colorado.

ALLEGED SHIPMENT: On or about June 30, 1951, by the Hope Co., from Maplewood, Mo.

PRODUCT: 5 gross bottles of *Hope mineral tablets* at Denver, Colo., together with 5 newspaper mats.

RESULTS OF INVESTIGATION: Advertisements were printed from two of the newspaper mats, and clippings of the advertisements were displayed with the article.

LABEL, IN PART: (Bottle) "Hope Mineral Tablets Dietary Supplement Each tablet contains 20 mgm. of Iron and traces of other minerals (extracted from a natural clay) plus ½ mgm. Vitamin B_1, 1 mgm. Vitamin B_2, 5 mgm. Niacin and ½ mcg. Vitamin B_{12}."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of arthritis, stomach ailments, neuritis, rheumatism, headaches, weak kidneys, dizzy spells, nervousness, bloating, acids, toxins, lack of vitality and energy, aching back, lumbago, underweight, decaying teeth, failing eyesight, bad complexion, frequent rising at night, leg pains, sleepless nights, suffering, lack of ambition and sparkle, and weakened powers, which were the conditions for which the article was offered in its labeling and advertising disseminated and sponsored by or on behalf of the distributor, the Hope Co. The article was misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the clippings of the newspaper advertisement, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, stomach ailments, neuritis, rheumatism, headaches, weak kidneys, dizzy spells, nervousness, bloating, acids, toxins, lack of vitality and energy, aching back, lumbago, underweight, decaying teeth, failing eyesight, bad complexion, frequent rising at night, leg pains, sleepless nights, suffering, lack of ambition and sparkle, and weakened powers. The article was not an adequate and effective treatment for such conditions. The article was misbranded in the above respect while held for sale after shipment in interstate commerce.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 8, 1951. Default decree of condemnation and destruction.

3608. Misbranding of radium chloride solution. U. S. v. 1 ampul * * *. (F. D. C. No. 31655. Sample No. 12820–L.)

LIBEL FILED: September 6, 1951, District of Colorado.

ALLEGED SHIPMENT: On or about August 7, 1951, by the United States Radium Corp., from New York, N. Y.

PRODUCT: 1 ampul of *radium chloride solution* at Denver, Colo. Examination indicated that the product contained a radium salt.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.

DISPOSITION: October 31, 1951. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3609. Adulteration of crude drug mixture. U. S. v. 6 Barrels * * *. (F. D. C. No. 31950. Sample No. 1719-L.)

LIBEL FILED: On or about October 30, 1951, Northern District of Georgia.

ALLEGED SHIPMENT: On or about April 2, 1945, from New York, N. Y.

PRODUCT: 6 110-pound barrels of *crude drug mixture* at Atlanta, Ga.

LABEL, IN PART: (Barrel) "Special Formula 643 Alex Senna Pumpkin Seed American Wormseed Anise Seed."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 3, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3610. Adulteration of phenobarbital tablets. U. S. v. 36 Bottles, etc. (F. D. C. No. 31750. Sample Nos. 25629-L, 25630-L, 25731-L.)

LIBEL FILED: October 3, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 21 and August 9, 1951, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: *Phenobarbital tablets.* 36 bottles of ¼-grain tablets and 32 bottles and 36 bottles of ½-grain tablets at Philadelphia, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the tablets purported to be and were represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and their strength differed from, and their quality fell below, that which they purported and were represented to possess. The tablets which were represented to contain ¼ grain of phenobarbital contained less than 94 percent of the labeled amount of phenobarbital and failed to meet the weight variation test laid down in the United States Pharmacopeia for individual tablets; the tablets in the 32-bottle lot which were represented to contain ½ grain failed to meet the weight variation test and the disintegration test laid down in the Pharmacopeia; and the tablets in the 36-bottle lot which were represented to contain ½ grain failed to meet the disintegration test.

DISPOSITION: December 3, 1951. Default decree of condemnation and destruction.

3611. Adulteration and misbranding of Estrotron. U. S. v. 15 Dozen Bottles, etc. (F. D. C. No. 31207. Sample No. 21027-L.)

LIBEL FILED: June 27, 1951, Northern District of Texas; amended libel filed on or about August 13, 1951.

ALLEGED SHIPMENT: On or about April 13, 1951, by the Pitman-Moore Co., Div. of Allied Laboratories, Inc., from Indianapolis, Ind.

*See also No. 3605.

PRODUCT: 15 dozen bottles of *Estrotron* at Dallas, Tex., together with accompanying leaflets entitled "Estrotron." A sample of this product was found to contain not more than 1.52 milligrams of estrogenic ketosteroids per cubic centimeter.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article which contained less than the declared amount of estrogenic ketosteroids per cubic centimeter: (Bottle label) "* * * Estrotron, 2 mg. (20,000 I. U.) per cc * * * consisting primarily of estrone with smaller amounts of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc. * * *" and (leaflet) "* * * containg 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc."

DISPOSITION: September 5, 1951. The Pitman-Moore Co., Div. of Allied Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Food and Drug Administration.

3612. Adulteration and misbranding of conjugated estrogens. U. S. v. 18 Bottles * * *. (F. D. C. No. 31308. Sample No. 10358–L.)

LIBEL FILED: July 2, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 30, 1951, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

PRODUCT: 18 bottles of *conjugated estrogens* at Detroit, Mich. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.83 mg. of sodium estrone sulfate per tablet.

RESULTS OF INVESTIGATION: The tablets were shipped from St. Louis, Mo., in a drum and repacked into bottles by the consignee at Detroit, Mich.

LABEL, IN PART: (Bottle) "100 Code No. 190 Sodestrin Tablets"; (drum) "Estrogen 1.25 Mg. Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement "Each * * * Tablet contains: Naturally-occurring water soluble Conjugated Estrogens equivalent in biological activity to 1.25 mg. of Sodium Estrone Sulfate" was false and misleading as applied to a product whose equivalent in biological activity was less than that declared.

DISPOSITION: August 30, 1951. Default decree of condemnation and destruction.

3613. Adulteration and misbranding of uterine capsules. U. S. v. 15 Boxes * * *. (F. D. C. No. 31604. Sample No. 21724–L.)

LIBEL FILED: August 6, 1951, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about March 14 and April 4, 1951, by the Globe Laboratories, from Fort Worth, Tex.

PRODUCT: 15 boxes each containing 1 dozen *uterine capsules* at New Orleans, La. Examination of the product showed that it contained no sodium perborate.

LABEL, IN PART: (Capsules) "Globe Uterine Capsules * * * Active Ingredients 100%: Sodium Perborate 39%, Boric Acid 60%, Iodoform 1%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess, namely, "Sodium Perborate 39%."

Misbranding, Section 502 (a), the label statement "Sodium Perborate 39%" was false and misleading as applied to an article which contained no sodium perborate.

DISPOSITION: September 6, 1951. Default decree of condemnation and destruction.

3614. Adulteration and misbranding of clinical thermometers. U. S. v. 48 Cartons * * *. (F. D. C. No. 31942. Sample No. 11205–L.)

LIBEL FILED: October 24, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about August 23, 1951, by the Cardinal Thermometer Co., from Brooklyn, N. Y.

PRODUCT: *Clinical thermometers.* 48 cartons, each containing 1 thermometer, and a leaflet entitled "Certificate of Accuracy for Clinical Thermometer" at Cleveland, Ohio.

Examination of 23 thermometers showed that 5 failed to comply with the Commercial Standard CS1–32 since 2 failed to give readings of required accuracy, 2 failed to meet the hard shaker test, and 1 failed to meet the test for entrapped gas.

LABEL, IN PART: (Carton) "Cardinal Fever Thermometer Oral."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the following statements in the leaflet were false and misleading as applied to an article which did not conform to the specifications set forth in CS1–32 Department of Commerce: "This certifies that the enclosed thermometer * * * has been tested on the above date at 98°, 102° and 106° F. and is correct within plus or minus 2/10 F. at any of these test points. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1–32 Department of Commerce)."

DISPOSITION: November 27, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3615. Misbranding of Diaplex. U. S. v. 21 Cartons, etc. (F. D. C. No. 31735. Sample No. 24156–L.)

LIBEL FILED: September 28, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about July 10, 1951, by H. W. Pierce, from Wellington, Colo.

PRODUCT: 21 cartons of *Diaplex* at Brooklyn, N. Y., together with a number of circulars entitled "The Successful Treatment of Diabetes." Analysis indicated that the product was a species of saltbush, such as *Atriplex canescens.*

*See also Nos. 3601, 3602, 3605, 3607, 3611–3614.

LABEL, IN PART: "Diaplex for Diabetics Net weight 12 ounces."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton label and in the accompanying circular were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for diabetes, heart, appendix, liver and kidney conditions, bloating of the stomach, diabetic gangrene, and gangrenous infection; and that it was effective to induce sleep and render unnecessary the use of insulin by diabetics. The article was not an adequate and effective treatment for such conditions.

Further misbranding, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug.

DISPOSITION: November 14, 1951. Default decree of condemnation and destruction.

3616. Misbranding of Quik-Kap capsules. U. S. v. 46,590 Capsules, etc. (F. D. C. No. 31973. Sample No. 36917–L.)

LIBEL FILED: November 15, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about September 7, 1951, from Newark, N. J.

PRODUCT: 46,590 *Quik-Kap capsules* at New York, N. Y., in the possession of the Personal Drug Co.

RESULTS OF INVESTIGATION: After receipt of the capsules from Newark, N. J., the consignee repackaged a number of the capsules into 21-capsule-size boxes. At the time of mailing to purchasers, there was inserted with each box in a mailing carton a leaflet entitled "Directions For The Use of Quik-Kaps." The consignee also had on hand a number of leaflets and loose labels used in repacking the bulk material.

LABEL, IN PART: (Box) "Quik-Kap Capsules * * * 21 Capsules * * * Active Ingredients: Black Cohosh (Powd. Ext. Cimicifuga) 0.0065 Gm. Wind Flower (Powd. Ext. Pulsatilla) 0.0065 Gm. Ferrous Sulfate U. S. P., Manganese Dioxide, Thiamine Hydrochloride U. S. P. (vit. B_1) 0.001 Gm."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the box label and in the leaflet were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for delayed or irregular menstruation, whereas the article was not an adequate and effective treatment for such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 30, 1951. Default decree of condemnation and destruction.

3617. Misbranding of vitamin tablets. U. S. v. 720 Packages, etc. (F. D. C. No. 31227. Sample Nos. 23825–L, 23826–L.)

LIBEL FILED: June 29, 1951, District of New Jersey.

ALLEGED SHIPMENT: Approximately 6 years prior to the date of the libel, by Major Vitamins, Inc., from New York, N. Y.

PRODUCT: 1,296 packages of *vitamin tablets* at Bound Brook, N. J.

LABEL, IN PART: (Package) "Major-B Brand Natural Vitamin B Complex with added thiamine Tablets [or "Major B Complex Brand Natural Vitamin Tablets"]."

	Each Tablet		(3 Tablets)
	Milligrams	*Micrograms*	*Micrograms*
Thiamine (Vitamin B_1)	.333	333	1,000
Riboflavin (Vitamin B_2)	0.166	166	500
Pyridoxine (Vitamin B_6)	0.026	26	80
Pantothenic Acid	0.083	83	250
Niacin	0.166	166	500

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet entitled "Buoyant Health For All The Family," which was enclosed in each package of the article, were false and misleading. The statements represented and suggested that the article was effective to provide greater energy, steadier nerves, better digestion, improved health and vigor, better appetite, insurance from vitamin deficiencies, and physical well-being, and protection against frequent colds, constipation, fatigue, digestive upsets, and other common ills; that the article provided the vitamins found in whole wheat bread, eggs, milk, liver, and tomato juice; that there are widespread dietary deficiencies that would be corrected by use of the article; that the article contained nutritionally significant amounts of all vitamins of the B-complex; that foods are an unreliable source of vitamins for the reasons specified; and, therefore, that it was desirable, if not necessary, to supplement the ordinary diet with the article. The article was not capable of fulfilling the promises of benefit made for it.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 9, 1951. Default decree of condemnation and destruction.

3618. Misbranding of Savory. U. S. v. 21 Jars * * *. (F. D. C. No. 31142. Sample Nos. 9892–L.)

LIBEL FILED: May 28, 1951, Northern District of Illinois.

ALLEGED SHIPMENT: On or about March 16, 1951, from New York, N. Y.

PRODUCT: 21 1-pound jars of *Savory* at Chicago, Ill., in possession of the Stanton Natural Food Co.

RESULTS OF INVESTIGATION: The article was shipped to Chicago in a number of 10-pound cans, and after receipt by the consignee it was repackaged into 1-pound jars and relabeled.

LABEL, IN PART: (Can) "Vegex Brand of Yeast Vegetable Extract with added Salt and Iron * * * One level teaspoonful (6 grams) supplies the listed percentages and amounts of the minimum daily adult requirements: 54% Vitamin B_1 (0.54 mg.) 14% Riboflavin (0.28 Mg.) 42% Iron (4.2 mg.) 4.2 mg. Niacin All other members of the B Complex natural to yeast the need for which in human nutrition has not been established"; (jar) "Savory A Splendid Blood Builder."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the jar label were false and misleading since the article was not effective for building blood, and it was not effective in the treatment of the conditions stated and implied: "A Splendid Blood Builder * * * Nervousness * * * Indigestion * * * Loss of appetite * * * Constipation * * * Gas in the intestines * * * Colitis * * * Headache * * * Anemia * * * Heart Failure * * * Cerebral Hemorrhage * * * Loss of vigor

and pep * * * poor general health Savory produces remarkable results for those suffering with the above disorders."

Further misbranding, Section 502 (b) (2), the article was a drug in package form, and it failed to bear a label containing an accurate statement of the quantity of the contents.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 24, 1951. Default decree of condemnation and destruction.

3619. Misbranding of Golden Rub. U. S. v. 10 Cases * * *. (F. D. C. No. 31345. Sample No. 18251–L.)

LIBEL FILED: July 17, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about May 15, 1951, by Dr. A. Zaugg, from Los Angeles, Calif.

PRODUCT: 10 cases, each containing 12 1-pint bottles, of *Golden Rub* at Tucson, Ariz. Analysis showed that the product contained ammonia and ammonium salts of organic acids, including salicylic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in a leaflet entitled "Golden Rub" attached to each bottle were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis, neuritis, bursitis, rheumatism, and psoriasis, whereas the article was not an adequate and effective treatment for such conditions.

DISPOSITION: October 2, 1951. Default decree of condemnation and destruction.

DRUG FOR VETERINARY USE

3620. Misbranding of Campbell's Chemical Mix. U. S. v. 46 Cartons * * *. (F. D. C. No. 31384. Sample No. 13115–L.)

LIBEL FILED: August 3, 1951, District of Montana.

ALLEGED SHIPMENT: On or about July 3, 1951, by the S. & L. Campbell Co., from Dupont, Colo.

PRODUCT: 46 3-pound cartons of *Campbell's Chemical Mix* at Martinsdale, Mont. Examination showed that the product consisted of ammonium chloride, potassium chlorate, and sodium chlorate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading: "Campbell's Chemical Mix for Cattle and Sheep" and (instructions for feeding sheep and cattle on alfalfa or clover) "* * * put one 3-lb. package of Campbell's Chemical Mix to 100 lbs. No. 4 salt and mix thoroughly. Put in troughs where they can have access to it at all times. When feeding dairy cows chop or bran, put ¼ teaspoonful in the chop or bran twice daily out of the 3-lb. package. For drench, mix one teaspoonful in ¾ quart of water and drench * * * We recommend force feeding when grain is fed—feed about 2 or 3 days before turning on clover or alfalfa." (The product would not be effective for the purposes suggested and implied.)

DISPOSITION: October 18, 1951. Default decree of condemnation and destruction.

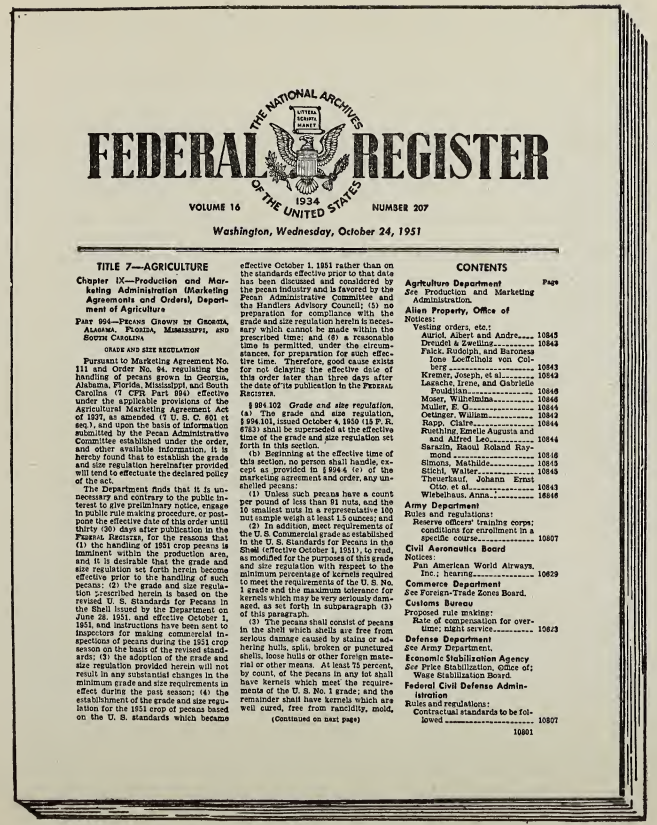
INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3601 TO 3620

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3601) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1952



THE NATIONAL ARCHIVES
LIBERTY SECURITY MARKET
1934
OF THE UNITED STATES

FEDERAL REGISTER

VOLUME 16 NUMBER 207

Washington, Wednesday, October 24, 1951

TITLE 7—AGRICULTURE

Chapter IX—Production and Marketing Administration (Marketing Agreements and Orders), Department of Agriculture

Part 904—Pecans Grown in Georgia, Alabama, Florida, Mississippi, and South Carolina

GRADE AND SIZE REGULATION

Pursuant to Marketing Agreement No. 111 and Order No. 94, regulating the handling of pecans grown in Georgia, Alabama, Florida, Mississippi, and South Carolina (7 CFR Part 904) effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.), and upon the basis of information submitted by the Pecan Administrative Committee established under the order, and other available information, it is hereby found that to establish the grade and size regulation hereinafter provided will tend to effectuate the declared policy of the act.

The Department finds that it is unnecessary and contrary to the public interest to give preliminary notice, engage in public rule making procedure, or postpone the effective date of this order until thirty (30) days after publication in the Federal Register, for the reasons that (1) the handling of 1951 crop pecans is imminent within the production area, and it is desirable that the grade and size regulation set forth herein become effective prior to the handling of such pecans; (2) the grade and size regulation prescribed herein is based on the revised U. S. Standards for Pecans in the Shell issued by the Department on June 28, 1951, and effective October 1, 1951, and instructions have been sent to inspectors for making commercial inspections of pecans during the 1951 crop season on the basis of the revised standards; (3) the adoption of the grade and size regulation provided herein will not result in any substantial changes in the minimum grade and size requirements in effect during the past season; (4) the establishment of the grade and size regulation for the 1951 crop of pecans based on the U. S. standards which became effective October 1, 1951 rather than on the standards effective prior to that date has been discussed and considered by the pecan industry and is favored by the Pecan Administrative Committee and the Handlers Advisory Council; (5) no preparation for compliance with the grade and size regulation herein is necessary which cannot be made within the prescribed time; and (6) a reasonable time is permitted, under the circumstances, for preparation for such effective time. Therefore, good cause exists for not delaying the effective date of this order later than three days after the date of its publication in the Federal Register.

§ 904.102 *Grade and size regulation.* (a) The grade and size regulation, § 904.101, issued October 4, 1950 (15 F. R. 6783) shall be superseded at the effective time of the grade and size regulation set forth in this section.

(b) Beginning at the effective time of this section, no person shall handle, except as provided in § 904.6 (e) of the marketing agreement and order, any unshelled pecans:

(1) Unless such pecans have a count per pound of less than 91 nuts, and the 10 smallest nuts in a representative 100 nut sample weigh at least 1.5 ounces; and

(2) In addition, meet requirements of the U. S. Commercial grade as established in the U. S. Standards for Pecans in the Shell (effective October 1, 1951), to read, as modified for the purposes of this grade and size regulation with respect to the minimum percentage of kernels required to meet the requirements of the U. S. No. 1 grade and the maximum tolerance for kernels which may be very seriously damaged, as set forth in subparagraph (3) of this paragraph.

(3) The pecans shall consist of pecans in the shell which shells are free from serious damage caused by stains or adhering hulls, split, broken or punctured shells, loose hulls or other foreign material or other means. At least 75 percent, by count, of the pecans in any lot shall have kernels which meet the requirements of the U. S. No. 1 grade; and the remainder shall have kernels which are well cured, free from rancidity, mold,

(Continued on next page)

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3621–3640

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 1, 1952.*

CONTENTS *

*For presence of a habit-forming narcotic without warning statement, see Nos. 3621–3623; omission of, or unsatisfactory, ingredients statements, Nos. 3621, 3622, 3634; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3621–3623; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3621.

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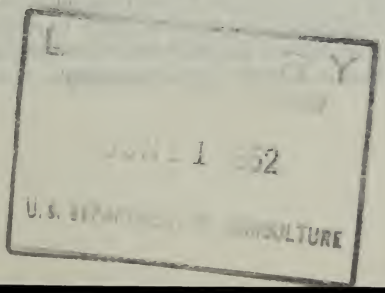

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3621. Adulteration and misbranding of ear wax drops and Alom Jel and misbranding of Vita-Malt, Eph-Thol nose drops, Pyrinimate, Pyrinimate tablets, hydrogen peroxide, milk of magnesia, and calamine lotion. U. S. v. 10,000 Bottles, etc. (F. D. C. No. 31639. Sample Nos. 18271–L to 18280–L, incl.)

LIBEL FILED: August 23, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about May 7, 8, 14, 17, 18, 21, and 28, 1951, from Burbank and Los Angeles, Calif. The products were shipped to Phoenix, Ariz., and with the exception of the *Vita-Malt*, were either labeled or repacked and labeled while held for sale after such shipment.

PRODUCT: 10,000 bottles of *Vita-Malt;* 21 cases, each containing 48 bottles, of *Eph-Thol nose drops;* 11 cases, each containing 48 bottles, or *ear wax drops;* 53 cases, each containing 24 bottles, of *Alom Jel;* 98 bottles of *Pyrinimate;* 1 drum containing 25,000 25 mg. *Pyrinimate tablets* and 1 drum containing 25,000 50 mg. *Pyrinimate tablets;* 12 cases, each containing 24 bottles, of *hydrogen peroxide;* 17 cases, each containing 4 bottles, of *milk of magnesia;* and 8 bottles of *calamine lotion.*

Analysis showed that the *Eph-Thol nose drops* consisted of an aqueous solution containing 0.99 percent ephedrine sulfate, chlorobutanol (a chloral derivative), and a small proportion of menthol; that the *ear wax drops* contained approximately 4.8 percent phenol; that the *Alom Jel* contained 2.32 percent of aluminum oxide in the form of aluminum hydroxide and hydrated oxide (the United States Pharmacopeia provides that aluminum hydroxide gel shall contain not less than 3.6 percent of aluminum oxide in the form of aluminum hydroxide and hydrated oxide); that the *Pyrinimate* and the *Pyrinimate tablets* contained pyrilamine maleate, with the 50-milligram tablet containing approximately 41.5 milligrams of pyrilamine maleate per tablet; that the *hydrogen peroxide* was short volume; and that the *calamine lotion* contained glycerin and lime water, ingredients not specified in the formula for this article as set forth in the currently official United States Pharmacopeia, and did not contain polyethylene glycol 400 monostearate which is specified as an ingredient of the formula in the currently official United States Pharmacopeia.

LABEL, IN PART: "1 Lb. Size RC Vita-Malt Standardized," "RC Eph-Thol (Ephedrine Menthol) Nose Drops One Ounce," "RC Ear Wax Drops One Ounce Phenol 1% and Glycerine," "One Pint RC Alom Jel Aluminum Hydroxide Gel," "One Pt. RC Hydrogen Peroxide," "One Gal. RC Milk of Magnesia U. S. P.," and "One Gal. RC Calamine Lotion U. S. P. Packaged By Contract For R & C Co., Nutley, N. J.," and "R & C Pyrinimate Anti-Histamine Pyrinilamine Maleate 2.5 mg. Suerose – Glycerine [or "R & C Pyrinimate Tablets Anti-Histamine Pyrinilamine Maleate 25 mg. [or 50 mg.]] Packed by Contract For R & C Co., Nutley, N. J."

NATURE OF CHARGE: Adulteration, Section 501 (b), the *Alom Jel* purported to be and was represented as "Aluminum Hydroxide Gel," a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from that set forth in such compendium; and, Section 501 (c), the strength of the *ear wax drops* differed from that which it was represented to possess, namely, phenol 1 percent.

Misbranding, Section 502 (b) (1), the labels of each of the articles failed to bear the name and place of business of the manufacturer, packer, or distributor. (There was no R & C Co. of Nutley, N. J., as declared upon the labels of the articles.)

Further misbranding, Section 502 (a), the label statement "Pyrinilamine Maleate 50 mg." on the label of a portion of the *Pyrinimate tablets* was false and misleading as applied to an article containing less than 50 mg. of pyrilamine maleate, and the label designation "U. S. P." on the label of the *calamine lotion* was false and misleading as applied to an article, the identity of which differed from that listed in the current revision of the United States Pharmacopeia; and, Section 502 (b) (2), the *hydrogen peroxide* failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Eph-Thol nose drops* contained a chemical derivative of chloral, namely, chlorobutanol, which derivative has been found to be and by regulations designated as, habit forming; and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the label of the *Eph-Thol nose drops* failed to bear the common or usual name of each active ingredient since ephedrine sulfate was not declared, and the label of the *Pyrinimate* and the *Pyrinimate tablets* failed to bear the common or usual name of each active ingredient since pyrilamine maleate was not declared; and, Section 502 (j), the *ear wax drops* were dangerous to health when used in the dosage prescribed in the labeling.

The articles were adulterated and misbranded as described above while held for sale after shipment in interstate commerce.

DISPOSITION: On or about November 29, 1951, the Kimball Drug Co., Phoenix, Ariz., having appeared as claimant, judgment of condemnation was entered and the court ordered that the products be released under bond for reprocessing and relabeling to comply with the law, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3622. Misbranding of Dexedrine Sulfate tablets, Gantrisin tablets, and Seconal Sodium capsules. U. S. v. Gary Drug Co., Inc., Jacob H. Raverby, and Tobias Levine. Pleas of guilty. Fine of $200 against corporation and $50 against each individual. (F. D. C. No. 31244. Sample Nos. 79826–K, 79832–K, 79982–K, 79983–K, 79985–K to 79987–K, incl., 79991–K to 79995–K, incl.)

INFORMATION FILED: November 8, 1951, District of Massachusetts, against the Gary Drug Co., Inc., Boston, Mass., Jacob H. Raverby, president and treasurer of the corporation, and Tobias Levine, a pharmacist employed by the corporation.

INTERSTATE SHIPMENT: From the States of Pennsylvania, New Jersey, and Indiana, into the State of Massachusetts, of quantities of *Dexedrine Sulfate tablets*, *Gantrisin tablets*, and *Seconal Sodium capsules*.

*See also No. 3640 (veterinary preparations).

ALLEGED VIOLATION: On or about September 7, 8, 13, 14, 19, and 28, and October 2, 6, and 10, 1950, while the drugs were being held for sale at the Gary Drug Co., Inc., after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The Gary Drug Co., Inc., and Jacob H. Raverby were made defendants in all counts, and Tobias Levine was joined as a defendant in three of the counts involving sales made by him.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (e) (1), the label of the repackaged *Dexedrine Sulfate tablets* failed to bear the common or usual name of the drug; and, Section 502 (e) (2), the repackaged *Gantrisin tablets* failed to bear the common or usual name of each active ingredient of the drug.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *Gantrisin tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users.

DISPOSITION: November 23, 1951. Pleas of guilty having been entered, the court imposed a fine of $200 against the corporation and $50 against each individual.

3623. Misbranding of pentobarbital sodium capsules. U. S. v. Stanley's Beach Pharmacy, Albert B. McCully, and Robert I. Stanley. Pleas of nolo contendere. Fine of $100 against pharmacy; sentence withheld against individuals and each placed on probation for 2 years. (F. D. C. No. 29120. Sample Nos. 1850–K, 1851–K, 1859–K, 1861–K, 1862–K, 63665–K.)

INFORMATION FILED: June 1, 1950, Southern District of Florida, against Stanley's Beach Pharmacy, a partnership, Fort Lauderdale, Fla., Albert B. McCully, a partner in the firm, and Robert I. Stanley, a pharmacist for the firm.

INTERSTATE SHIPMENT: From the State of Georgia into the State of Florida, of quantities of *pentobarbital sodium capsules.*

ALLEGED VIOLATION: On or about May 25, and June 3, 10, 25, 27, and 28, 1949, while the drug was being held for sale at Stanley's Beach Pharmacy after shipment in interstate commerce, various quantities of the capsules were repacked and sold without a prescription, which acts resulted in the capsules being misbranded.

Stanley's Beach Pharmacy was charged with causing the acts of repacking and sale of the drug involved in each of the 6 counts of the information; and

Robert I. Stanley, in 4 counts, and Albert B. McCully, in 2 counts, were charged with the sales made in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the drug failed to bear the name, and quantity or proportion of such derivative and the statement "Warning—May be habit forming."

DISPOSITION: October 5, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of $100 against the partnership, withheld sentence against the individuals, and placed each individual on probation for 2 years.

3624. Misbranding of Special Prescription tablets and Aciduric tablets. U. S. v. 1 Drum, etc. (F. D. C. No. 31719. Sample Nos. 11314–L, 11315–L.)

LIBEL FILED: September 21, 1951, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 3 and September 11, 1950, by the Barlow-Maney Laboratories, from Cedar Rapids, Iowa.

PRODUCT: 1 drum containing 4,900 tablets designated "Special Formula tablets" and 57 bottles of tablets which had been repackaged from this drum by the consignee and labeled *Special Prescription tablets*; and 1 drum containing 14,900 tablets designated "Special Formula tablets" and 57 boxes of tablets which had been repackaged from the latter drum by the consignee and labeled *Aciduric tablets*. The products were located at Glendale, Ohio, and were accompanied by a number of labels, circulars entitled "Price List," and leaflets entitled "Special Notice."

Analysis indicated that the 4,900 tablets in one of the drums possessed essentially the composition stated upon the drum label and that the 14,900 tablets in the other drum contained approximately 5.4 grains of sodium salicylate per tablet.

LABEL, IN PART: (4,900-tablet drum) "Special Formula Tablets C. C. T. Each tablet contains as active ingredients: Po Iodized Lime 1/4 gr. (Represents a mixture of Iodine and Iodide of Calcium) Sodium acetate 1/4 gr. Sodium Nitrite 1 gr. Nitroglycerine Q. S. (1/1000 grain added at time of manufacture) * * * From the Laboratories of Arlo Co. * * * Cedar Rapids, Iowa"; (bottle) "Special Prescription Tablets * * * This package contains 75 tablets Each tablet contains: Iodized Lime 1/4 gr. Sodium Acetate 1/4 gr. Sodium Nitrite 1 gr. Sodium Bicarbonate 2 gr. Nitroglycerine 1–1000 gr. F. E. Crataegus 1 min."

(14,900-tablet drum) "Special Formula Tablets Each tablet contains: Sodium Salicylate, Powdered Cimicfugin, Powdered Phytolaccin and P. E. Burdock Root * * * From the Laboratories of Arlo Co. * * * Cedar Rapids, Iowa"; (box) "Landis Aciduric Tablets * * * Each Aciduric tablet contains: Sodium Salicylate 5 grains Powdered Cimicfugin 1/2 grain Phytolaccin 1/8 grain P. E. Burdock Root 1 grain This package contains 50 tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the tablets in the drums, bottles, and boxes were false and mislead-

ing. The statements represented and suggested that the tablets in the 4,900-tablet drum and in the bottles were an adequate and effective treatment for high blood pressure, and that the tablets in the 14,900-tablet drum and in the boxes were an adequate and effective treatment for rheumatism, joint pains, stiffness, and similar ailments and complaints. The articles were not adequate and effective treatments for such conditions.

Further misbranding, Section 502 (f) (1), the labeling of the tablets in the 4,900-tablet drum and in the bottles failed to bear adequate directions for use. The tablets were misbranded in this respect when introduced into, while in, and while held for sale after shipment in, interstate commerce.

Further misbranding, Section 502 (a), certain statements in the labeling of the tablets in the 14,900-tablet drum were false and misleading. The statements represented and suggested that powdered cimicifugin and phytolaccin are the common or usual names of drugs and that "P. E. Burdock Root" was an active ingredient. Powdered cimicifugin and phytolaccin are not the common or usual names of any substances, and "P. E. Burdock Root" was not an active ingredient of the tablets. The tablets were misbranded in this respect when introduced into and while in interstate commerce.

DISPOSITION: October 26, 1951. The R. Landis Co., Glendale, Ohio, claimant, having consented to the entry of a decree and admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the tablets be released under bond for relabeling under the supervision of the Federal Security Agency.

3625. Misbranding of vitamin and caffeine capsules. U. S. v. 200 Cartons, etc. (F. D. C. No. 30811. Sample Nos. 28011–L, 28012–L, 28020–L.)

LIBEL FILED: February 27, 1951, Northern District of California.

ALLEGED SHIPMENT: On or about January 12, 1951, by the Preston Laboratories, and or about January 26 and February 6, 1951, by National Drug Laboratories, Inc., from Chicago, Ill.

PRODUCT: Vitamin and caffeine capsules. 200 cartons, each containing 28 vials; 2 fiber drums, each containing 104,000 capsules, and 1 fiber drum containing 102,500 capsules, at San Francisco, Calif., in possession of the Mapco Pharmacal Co., together with a number of vial and carton labels and other pieces of literature.

RESULTS OF INVESTIGATION: The capsules were shipped in fiber drums from Chicago to the Mapco Pharmacal Co., which repacked a number of the capsules into vials. The vials then were packed into cartons and were offered for sale with literature entitled "Are you suffering from T. F.? * * * Try Mapco Anti-Fatigue Kaps * * * T. F. (tired feeling)."

LABEL, IN PART: (Drums) "Private Formula 104,000 Bulk Capsules [or "102.500 Capsules"] * * * Each Capsule Contains: Thiamin HCl 5 mg. (5 MDR) Riboflavin 2.5 mg. (1¼ MDR) Niacinamide 10 mg. Vitamin B–12 (as in Streptomyces Fermentation Extractives) 2.5 mcg. Caffeine Citrate 2.5 gr. * * *"; (vials) "25 Mapco Kaps. Anti-Fatigue Kaps for that tired feeling * * * No Subsequent Depression * * * Dose: One capsule in the morning and afternoon. This product contains those basic vitamins, the lack of which often cause that 'tired' 'run down' feeling plus the blood building Vitamin B_{12} and stimulating caffeine.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the capsules in the drums failed to bear adequate directions for use. The cap-

sules were misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the capsules in the vials, namely, the carton and vial labels and the above-mentioned literature, was false and misleading. The labeling contained statements which represented and suggested that the capsules when taken as directed were effective to relieve fatigue and that tired, run-down feeling; for blood building; and to provide a quick pick-up with no subsequent depression. The capsules when taken as directed were not effective for such purposes. The capsules were misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 26, 1951. The Mapco Pharmacal Co. having filed a claim in the case and subsequently having defaulted in taking any further action, judgment of condemnation was entered and the court ordered that the product be destroyed.

3626. Misbranding of Special Family-Pak vitamin capsules and mineral tablets. U. S. v. 43 Packages * * *. (F. D. C. No. 28733. Sample Nos. 68505-K, 68507-K, 68517-K.)

LIBEL FILED: March 2, 1950, Western District of Washington; amended libel filed March 25, 1950.

ALLEGED SHIPMENT: On or about February 6, 17, and 23, 1950, from Lynwood, Calif.

PRODUCT: 43 packages of *Special Family-Pak vitamin capsules and mineral tablets* at Seattle, Wash., in the possession of Nutritional Products.

RESULTS OF INVESTIGATION: The product was promoted by means of printed matter on the subject of nutrition and through oral representations made by Mrs. Judith A. Norberry, owner of Nutritional Products, and a salesman for Mrs. Norberry. A copy of a form letter on the letterhead of Nutritional Products and beginning "Dear —— Several days ago, we mailed you a copy of an article on Heart Disease which appeared in Coronet Magazine," a reprint of an article in the October 1948 issue of Coronet Magazine entitled "For Heart Disease: Vitamin E by J. D. Ratcliff," a booklet entitled "You can have A Life Worth Living," and reprints entitled "'E' Found To Avert Menopausal Pains" and "Vitamin E May Hand 'Knockout' to Surgery Killer" were distributed by Nutritional Products through the mails or personally by Mrs. Norberry and the salesman. Oral representations were made by both individuals during sales talks with prospective customers.

LABEL, IN PART: "Special Family-Pak with Hy E Supplemental Nutrition This package contains: 60 Multiple Vitamin Capsules—90 Hy E Perles 90 Mineral Tablets Two red vitamin capsules, three yellow E perles and three mineral tablets (suggested daily intake) supply the following amounts and proportions of minimum daily adult requirements: Vitamin A 25,000 USP units . . . 624% Vitamin D 2,000 USP units . . . 500% Vitamin B_1 10 Mg. . . . 1000% Vitamin B_2 10 Mg. . . . 500% Vitamin B_6 2 Mg. Vitamin C 300 Mg. . . . 1000% Calcium Pantothenate 20 Mg. Niacin Amide USP 100 Mg. Vitamin E (90 Int. Units or) 90 Mg. Calcium 750 Mg. . . . 100% Phosphorus 380 Mg. . . . 50% Iron 10 Mg. . . . 100% Copper 0.1 Mg. Iodine 0.2 Mg. . . . 200% Para Aminobenzoic Acid 15 Mg. Chlorophyll 1 Mg. Inositol 15 Mg. Folic Acid 1 Mg. Rutin 1 Mg. Fluorine 0.2 Mg. Kelp 6 Grs."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, the accompanying booklets, reprints, and form letter, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for coronary, anginal, hypertensive, and rheumatic heart disease; for anginal pain; for high blood pressure; for increasing the body's resistance to infections, especially of the respiratory tract; for promoting growth in children; for preventing conjunctivitis, pain, paralysis, neuritis, shingles, sprue or celiac disease, infections, sterility, paralysis of muscle tissues, and deterioration of mental vigor and the ability to think clearly or for long periods; for preventing nervous, mental, muscular, skin, and digestive upsets; for providing endurance; for healing wounds; for counteracting acids; for nourishing the brain and nerves; by acting as a tonic for promoting vitality; for providing energy and vitality; for protecting against physical unsoundness; for providing a body fit for an active and forceful spirit; and for preventing menopausal pain and thrombosis. The article was not an adequate and effective treatment for such conditions and purposes.

The libel alleged further that if the allegations that the above-mentioned booklets, reprints, and letter were part of the labeling of the product are not upheld by the court, then the article was further misbranded under Section 502 (f) (1) in that the labeling failed to bear adequate directions for use in the conditions named in the previous paragraph.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in asthma, bronchitis, arthritis, rheumatism, loss of hair, colds, nervousness, and eczema in children; for use in improving the keenness of mind in children; for use in the treatment of incipient cataracts; for use in lung conditions; and for use in the prevention of cancer, which were the conditions for which the article was intended by the distributor.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: October 24, 1951. Judith A. Norberry, claimant, having consented to the entry of a decree without admitting the truth of the allegations of the libel, judgment of condemnation was entered and the court ordered that the product and the printed and graphic matter be destroyed.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3627. Adulteration of orrisroot. U. S. v. 181 Bags * * *. (F. D. C. No. 30917. Sample No. 24004–L.)

LIBEL FILED: April 12, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about November 23, 1948, from New York, N. Y.

PRODUCT: 181 bags, each containing 110 pounds, of *orrisroot* at Bayonne, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

The article was alleged also to be adulterated under the provisions of the law applicable to cosmetics, as reported in notices of judgment on cosmetics, No. 193.

DISPOSITION: July 2, 1951. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3628. Adulteration of phenobarbital tablets. U. S. v. 4 Bottles, etc. (F. D. C. No. 31399. Sample Nos. 25563–L, 25565–L.)

LIBEL FILED: July 27, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about May 25, 1951, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: *Phenobarbital tablets.* 4 25,000-tablet bottles, 12 1,000-tablet bottles, and 20 5,000-tablet bottles of green tablets, and 1 drum of 280,000 tablets, and 15 1,000-tablet bottles, 8 5,000-tablet bottles, and 3 25,000-tablet bottles of white tablets at Philadelphia, Pa.

RESULTS OF INVESTIGATION: The interstate shipment of the tablets was made in bulk containers. After receipt of the shipment, a portion of the tablets was repackaged into bottles and relabeled by the consignee.

Analysis showed that the green tablets contained not more than 62 percent of the labeled amount of phenobarbital, whereas the United States Pharmacopeia provides that phenobarbital tablets contain not less than 94 percent of the labeled amount of phenobarbital. Further analysis showed that the white tablets failed to meet the test specified in the United States Pharmacopeia regarding permissible variation in the weight of individual tablets and the time required by the tablets to disintegrate in water.

LABEL, IN PART: (Bottle) "Phenobarbital ½ Grain * * * Green [or "White"]."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as "Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and the strength (green tablets) differed from, and the quality (white tablets) fell below, the standard set forth in the compendium. The tablets were adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: November 29, 1951. Default decree of condemnation and destruction.

3629. Adulteration and misbranding of Estrotron (estrogenic hormone). U. S. v. 9 Dozen bottles * * *. (F. D. C. No. 31208. Sample No. 28281–L.)

LIBEL FILED: June 21, 1951, Northern District of California.

ALLEGED SHIPMENT: On or about July 6 and 31, 1950 by the Pitman-Moore Co., Div. of Allied Laboratories, Inc., from Indianapolis, Ind.

PRODUCT: 9 dozen bottles of *Estrotron* at Sacramento, Calif. Examination showed that the product contained not more than 1.64 milligrams of estrogenic ketosteroids per cubic centimeter.

LABEL, IN PART: (Bottle and carton) "10 cc. Size * * * Estrotron 2 mg. (20,000 I. U.) per cc. in Peanut Oil A highly purified estrus producing extract from the urine of pregnant mares, consisting primarily of estrone with smaller quantities of naturally occurring estrogens, dissolved in Peanut Oil and standardized to 20,000 I. U. of activity per cc."

*See also No. 3621.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the product contained less than the declared amount of estrogenic ketosteroids per cubic centimeter: (Bottle and carton label) "* * * Estrotron 2 mg. (20,000 I. U.) per cc. * * * consisting primarily of estrone with smaller quantities of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc. * * *" and (accompanying leaflet entitled "Estrotron") "* * * containing 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc."

DISPOSITION: October 29, 1951. The shipper having appeared as claimant and admitted that the product was below potency, judgment of condemnation was entered and the court ordered that the product be released under bond to be reprocessed in compliance with the law, under the supervision of the Food and Drug Administration.

3630. Adulteration of uterine capsules. U. S. v. 69 Cartons * * *. (F. D. C. No. 31523. Sample No. 21901–L.)

LIBEL FILED: On or about September 14, 1951, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about April 30, 1951, by Globe Laboratories, from Fort Worth, Tex.

PRODUCT: 69 cartons of *uterine capsules* at New Orleans, La. Examination showed that the product contained no sodium perborate.

LABEL, IN PART: "Globe Uterine Capsules 1 Dozen * * * Active Ingredients 100%: Sodium Perborate 39%, Boric Acid 60%, Iodoform 1%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from, and its quality fell below, that which it was represented to possess, namely, "Sodium Perborate 39%."

DISPOSITION: October 11, 1951. Default decree of condemnation and destruction.

3631. Adulteration and misbranding of uterine capsules. U. S. v. 23 Cartons, etc. (F. D. C. No. 31904. Sample Nos. 20846–L, 20847–L.)

LIBEL FILED: October 17, 1951, Northern District of Alabama.

ALLEGED SHIPMENT: On or about April 3, May 9, and June 11, 1951, by the Globe Laboratories, from Fort Worth, Tex.

PRODUCT: *Uterine capsules.* 23 cartons, each containing 3 capsules, and 13 cartons, each containing 12 capsules, at Birmingham, Ala. Analysis showed that the product contained approximately 10 percent of the declared amount of sodium perborate.

LABEL, IN PART: "Globe Uterine Capsules Active Ingredients 100%: Sodium Perborate 39%."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 39 percent sodium perborate.

Misbranding, Section 502 (a), the label statement "Sodium Perborate 39%" was false and misleading as applied to this article, which contained less than 39 percent sodium perborate.

DISPOSITION: November 21, 1951. Default decree of condemnation and destruction.

3632. Adulteration of distilled water. U. S. v. 100 Vials * * *. (F. D. C. No. 31772. Sample No. 25740–L.)

LIBEL FILED: October 9, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about June 20, 1951, by the Harvey Laboratories, from Philadelphia, Pa.

PRODUCT: 100 vials of *distilled water* at Trenton, N. J.

LABEL, IN PART: "100 cc. Ampul-Vial Distilled Water Harvey (Triple Distilled) Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since it failed to meet the test for pyrogens laid down in such standard.

DISPOSITION: November 21, 1951. Default decree of condemnation. The court ordered that the product be destroyed, with the exception of 8 vials which were to be turned over to the Federal Security Agency.

3633. Adulteration and misbranding of Nervease headache powders. U. S. v. 12 Cartons * * *. (F. D. C. No. 31393. Sample No. 5645–L.)

LIBEL FILED: August 3, 1951, District of New Hampshire.

ALLEGED SHIPMENT: On or about May 25, 1951, by the Nervease Co., from Boston, Mass.

PRODUCT: 12 cartons, each containing 12 packages, of *Nervease headache powders* at Manchester, N. H. Examination showed that the product contained not more than 2.19 grains of acetanilid per powder.

LABEL, IN PART: (Package) "Nervease Headache Powders Active Ingredients: Acetanilid 2½ Grains Each Powder with Caffeine and Camphor * * * Contents 8 Powders."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 2½ grains of acetanilid per powder.

Misbranding, Section 502 (a), the designation "Nervease" appearing on the package label was false and misleading since such designation represented and suggested that the article was an adequate and effective treatment for nervous tension, whereas the article was not an adequate and effective treatment for such condition; and the label statement "Acetanilid 2½ Grains Each Powder" was false and misleading as applied to a product which contained less than the stated amount of acetanilid.

DISPOSITION: October 16, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3634. Misbranding of Diaplex. U. S. v. 23 Cartons * * *. (F. D. C. No. 31705. Sample No. 13633–L.)

LIBEL FILED: September 17, 1951, District of Idaho.

*See also Nos. 3621, 3624–3626, 3629, 3631, 3633.

ALLEGED SHIPMENT: On or about August 27, 1951, by John McVey, also known as H. W. Pierce, from Carr, Colo.

PRODUCT: 23 12-ounce cartons of *Diaplex* at Emmett, Idaho. Examination showed that the product consisted of ground plant material derived from a species of saltbush such as *Atriplex canescens*.

LABEL, IN PART: "Diaplex for Diabetics * * * for further information address c/o H. W. Pierce, Wellington, Colo."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since they represented and suggested that the article was an adequate and effective treatment for diabetes, and that use of the article by diabetics would render treatment with insulin unnecessary, whereas the article was worthless in the treatment of diabetes: "Diaplex for Diabetics * * * A diabetic should drink * * * Diaplex * * * watch the urine test daily and you will be amazed at the results * * * Persons using Diaplex with insulin should make the urine test daily, and as the pancreas increases its normal functions, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar, and eventually eliminate the insulin entirely. But continue the use of Diaplex until you are well and strong. Persons who have never used insulin, and not in coma, will find it unnecessary to do so. All that will be required is to adhere to a good diabetic diet and drink two quarts of Diaplex for a few months, and like thousands of others he, too, will rejoice in the grand activity of good health and vigor."

Further misbranding, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug.

DISPOSITION: November 5, 1951. Default decree of forfeiture and destruction.

3635. Misbranding of d-alphatocopheryl acetate capsules (Daland's Vit E Min Gelucaps). U. S. v. 1 Unlabeled Paper Bag, etc. (F. D. C. No. 28479. Sample No. 48592–K.)

LIBELS FILED: December 13, 1949, District of Delaware; amended libels filed May 1 and July 12, 1951.

ALLEGED SHIPMENT: On or about September 23, October 21, and November 3, 1949, from Newark, N. J.

PRODUCT: *d-alphatocopheryl acetate capsules.* 1 unlabeled paper bag containing 1,000 capsules; 23 bottles, each containing 100 capsules; 4 bottles, each containing 50 capsules; 1 bottle containing 1,000 capsules; and 2 bottles, each containing 500 capsules, in possession of the Daland Vitamin Co., Wilmington, Del.

The capsules had been repacked into the paper bag and bottles from the bulk containers in which they had been shipped in interstate commerce.

LABEL, IN PART: (Bottles) "Daland's Vit E Min Gelucaps 100 Mg. [or "30 Mg."] Alpha-Tocopherol."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a booklet entitled "Excerpts from the Treatment of Cardiovascular and Renal Diseases with Vitamin E 'Alpha Tocopherol,'" which accompanied the article were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for cardiovascular and renal diseases; that vitamin E therapy has the distinctive feature of improving the function of damaged hearts by attacking the underlying patho-

logical changes; that the article was an adequate and effective treatment for every common type of heart disease; that it was the most effective known medication in the treatment of heart disease; that it would decrease the anoxia of the cardiac muscle; that it would invade scar tissue with fresh blood vessels, thus softening or relaxing it; that it would decrease capillary fragility and permeability; that it would produce dilation of arterioles and venules; that it would prevent further thrombosis and help to resolve existing thrombi; that the digitalis requirement was often reduced after the administration of the article; that the article was an adequate and effective treatment for acute coronary thrombosis, older cases of coronary thrombosis, acute rheumatic fever, chronic rheumatic heart disease, anginal syndrome, hypertensive heart disease, acute hemorrhagic nephritis, indolent ulcers, thrombocytopenic purpura, thrombophlebitis, phlebothrombosis, early gangrene of the extremities, intermittent claudication, Buerger's disease, cerebral thrombosis, old coronary occlusion, acute rheumatism, rheumatic heart disease, phlebitis of the leg in pregnancy, diabetes mellitus, and diabetes in cardiac patients; and that the article would reduce the insulin requirement in diabetics and in diabetic cardiacs. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit implied, represented, and suggested.

Further misbranding, Section 502 (a), the label statement "Alpha-Tocopherol" was false and misleading as applied to an article which was d-alpha-tocopheryl acetate.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: Judson D. Ryon, trading as the Daland Vitamin Co., appeared as claimant and filed an answer denying that the product was misbranded. The Government subsequently filed a request for answers to certain written interrogatories, which the claimant answered in part and objected to in part. On November 27, 1951, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product and the accompanying labeling be destroyed.

3636. Misbranding of mineral tablets, B complex vitamins with iron tablets, and Mo Tee Na tablets. U. S. v. 59 Bottles, etc. (F. D. C. No. 31598. Sample Nos. 11297–L to 11299–L, incl.)

LIBEL FILED: August 7, 1951, Northern District of Ohio.

ALLEGED SHIPMENT: On or about April 24 and May 24, 1951, by the Mineral Food Co., from Indianapolis, Ind.

PRODUCT: 59 bottles of *mineral tablets*, 24 bottles of *B complex vitamins with iron tablets*, and 13 bottles of *Mo Tee Na tablets* at Millersburg, Ohio, together with copies of leaflets entitled "The M. F. Co.'s Vitamin B Complex" and "Mineral Supplement"; copies of a card entitled "Supplement Your Mineral and Vitamin Diet"; copies of mimeographed sheets entitled "Natures Minerals Vitamins," "Cochrane on the Ball," "Compare Our Formula With Any Advertisement in News Papers," "Important," and "Dr. William Brady Says"; and a copy of a mimeographed letter addressed "Good Morning Dear Friend."

LABEL, IN PART: (Bottles) "The M. F. Co's Minerals 270 Tablets * * * Contains: Potassium Iodide, Calcium Phosphate, Calcium Carbonate, Sodium Phosphate, Iron Sulfate Exsiccated, Sodium Chloride (iodized salt)";

"55 B Complex Vitamins With Iron * * * Contains Vitamin B_1 1 mg. (thiamin chloride) Vitamin B_2, .5 mg. (riboflavin) Niacin, 5 mg. Sodium Iron Pyrophosphate, 0.4 gr. Yeast plus inert compounding ingredients"; and "Mo Tee Na * * * Net Contents 100 Tablets * * * Active Ingredients: Calcium Succinate and Aspirin General Products Laboratories, Inc. 137 E. Spring St. Columbus, Ohio."

NATURE OF CHARGE: *Mineral tablets* and *B complex vitamins with iron tablets.* Misbranding, Section 502 (a), certain statements in the labeling of the articles, namely, in the above-mentioned leaflets, mimeographed sheets, card, and mimeographed letter, were false and misleading. The statements represented and suggested and created the impression (when read as a whole, as well as through specific statements) that the articles supplied a universal need; and that the articles were effective in reducing illness and increasing efficiency; in treating lack of resistance, loss of weight, congestion of blood, and weakness of muscles; in effecting normal nerve functioning, lactation, and reproduction and digestive actions; in preventing weakness of the legs, flabbiness of the heart muscles, and lowering of the body temperature; in maintaining health and strength; in fortifying the body against inroads of sickness; in antagonizing the aging process; in preventing a run-down condition; in correcting unnatural basic disorders that cause illness or disease regardless of their names; in making over physical wrecks, causing them to be happy, strong, free from stubborn suffering, pain and soreness of long duration, and able to sleep; in preventing the return of agonizing pain; in treating nervousness, stomach seeming to be tied up in a knot, insomnia, inability to work, and irritability; and in treating patients helpless with rheumatism, hay fever, hives, sick headache, "nervous" headache, allergy, crumbling teeth, excessive tooth decay, recurring or chronic spinal curvature, growing pains, adult tetany (cramps in legs or arms at night), recurring chilblains, and watery "drip-drip" from the nose, with fits of sneezing which many Yankee wiseacres ascribe to imaginary sinusitis which they think sounds better than "catarrh." The articles would not be effective for the purposes represented, suggested, and implied in the said statements.

Mo Tee Na tablets. Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, on the card entitled "Supplement Your Mineral and Vitamin Diet," were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for arthritis and neuritis, whereas the article would not be effective for such purposes.

The *mineral tablets* and *B complex vitamins with iron tablets* were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: October 5, 1951. Default decree of condemnation and destruction.

3637. Misbranding of Lavron cream. U. S. v. 2,940 Cases * * *. (F. D. C. No. 28989. Sample No. 54841-K.)

LIBEL FILED: May 9, 1950, Western District of Texas.

ALLEGED SHIPMENT: On or about January 4, 1950, by Lee Brothers Co., from Chicago, Ill.

PRODUCT: 2,940 cases, each containing 6 1-pound jars, of *Lavron cream* at San Antonio, Tex. Examination showed that the product consisted essentially of water, epsom salt, sodium sulfate, methyl salicylate, and stearates.

LABEL, IN PART: "Lavron Cream * * * Salferal Products Bay Springs, Mississippi."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "as a Reducing Plan for Normal Overweights * * * Helpful for * * * Swollen Feet" were false and misleading since the article was not effective for such purposes.

DISPOSITION: September 1951. N. C. Douglas, San Antonio, Tex., claimant, appeared and filed an answer to the libel. Requests for admissions subsequently were filed on behalf of the Government and were answered by the claimant. Thereafter, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law by relabeling under the supervision of the Federal Security Agency.

On November 15, 1951, the claimant having failed to withdraw the product from the custody of the marshal, and more than 30 days having passed since the entry of the decree, an order was entered upon motion of the Government directing that the product be destroyed.

3638. Misbranding of Vaporette device. U. S. v. 26 Devices, etc. (F. D. C. No. 29009. Sample No. 60052-K.)

LIBEL FILED: April 6, 1950, Northern District of Illinois.

ALLEGED SHIPMENT: On or about January 9, 1950, by M. F. Robertson Sons, Inc., from Lansdowne, Pa.

PRODUCT: 26 *Vaporette devices* at Chicago, Ill., together with a number of circulars entitled "Less Germs Less Colds with the Vaporette Glycol Vaporizer" and "Less Germs Fewer Colds."

Examination showed that the article was an electrically operated device for vaporizing glycols.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars accompanying the device were misleading since the statements represented and suggested and created the impression that by vaporizing glycol the device would prevent the spread of communicable diseases, whereas the vapors of glycol produced by the device were not effective to prevent the spread of communicable diseases.

DISPOSITION: November 29, 1951. Claimants for the devices having filed their appearance and answer, which were later withdrawn, judgment of condemnation was entered and the court ordered that the devices be destroyed.

DRUGS FOR VETERINARY USE

3639. Misbranding of Hess' condensed buttermilk for brood sows and laying hens. U. S. v. 10 Drums, etc. (F. D. C. No. 30817. Sample No. 19377-L.)

LIBEL FILED: February 23, 1951, Northern District of Iowa.

ALLEGED SHIPMENT: On or about January 12, 1951, from Omaha, Nebr.

PRODUCT: 10 drums, each containing 100 pounds, of *Hess' condensed buttermilk* at Miles, Iowa, together with a number of circulars.

RESULTS OF INVESTIGATION: The circulars were entitled "Hess' Brand Condenced Buttermilk," and were delivered to the consignee by Donald Hess of the Hess Condensed Buttermilk Co., Jesop, Iowa, about September 1950. A copy of these circulars was handed to purchasers.

LABEL, IN PART: (Drum) "Hess' Condensed Buttermilk For Brood Sows and Laying Hens."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars accompanying the article were false and misleading. These statements represented and suggested that the article was effective in the prevention and treatment of the disease of pigs known as "necro" or necrotic enteritis, whereas the article was not effective in the prevention and treatment of such disease. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 4, 1951. Default decree of condemnation. The court ordered that in lieu of destruction, the article be sold to the highest bidder, conditioned that it not be sold or otherwise disposed of in contravention of any law, and that it be disposed of solely for animal consumption. The court ordered further that the circulars accompanying the article be destroyed. (Editor's Note—Hess' condensed buttermilk for brood sows and laying hens was also published in notices of judgment on foods, No. 17623.)

3640. Misbranding of condition pills for dogs, triple bromide tablets, nerve sedative tablets, and urinary antiseptic tablets. U. S. v. 1 Drum, etc. (F. D. C. No. 30820. Sample Nos. 23696–L to 23698–L, incl.)

LIBEL FILED: March 2, 1951, District of Connecticut.

ALLEGED SHIPMENT: On or about March 10, June 20, and October 26, 1949, by Cowley Pharmaceuticals, Inc., from Worcester, Mass.

PRODUCT: 1 drum containing 45,000 pills, and 1,458 boxes, each containing 30 pills, of *condition pills for dogs;* 1 drum containing 6,000 tablets of *Triple bromide tablets;* 66 boxes, each containing 15 tablets, of *nerve sedative tablets;* and 1 drum containing 12,000 tablets, and 1,002 boxes, each containing 22 tablets, of *urinary antiseptic tablets* at New Haven, Conn., together with a quantity of labels for each of the products and a number of folders relating thereto entitled "Ranger Dog Manual On Common Ailments and General Symptoms."

LABEL, IN PART: "Condition Pills for dogs * * * Strychnine Arsenite 1–300 gr. Quinine Arsenate 1–60 gr. Iron Arsenate 1–60 gr. Nucleinic Acid 1–300 gr.," "Tablets Triple Bromide," "Nerve Sedative Tablets * * * Sodium Bromide 2½ gr. Potassium Bromide 2½ gr. Ammonium Bromide 2½ gr.," and "Urinary Antiseptic Tablets * * * Methenamine 5 gr."

NATURE OF CHARGE: *Condition pills for dogs.* Misbranding, Section 502 (a), the label statement "Condition Pills for dogs" was false and misleading since the statement represented and suggested that the article would restore dogs to a normal, healthy condition if they are out of condition, whereas the article would not accomplish such result. The article was misbranded in this respect when introduced into and while in interstate commerce. Further misbranding, Section 502 (a), certain statements on the box label and in the accompanying folder entitled "Ranger Dog Manual" were false and misleading since the statements represented and suggested that the article was effective to restore dogs to a normal, healthy condition regardless of condition before using, and to prevent skin rash and falling hair, and that it was effective in the treatment of unthriftiness, poor appetite, dull hair coat, and listlessness, whereas the article was not effective for such purposes. The article was misbranded in this respect while it was held for sale after shipment in interstate commerce.

Triple bromide tablets. Section 502 (f) (1), the labeling of the tablets in the bulk container failed to bear adequate directions for use. The tablets were misbranded when introduced into and while in interstate commerce.

Nerve sedative tablets. Misbranding, Section 502 (a), certain statements on the labels of the article and in the accompanying folder were false and misleading since the statements represented and suggested that the article was an effective treatment for fits, including those characterized by running and barking, whereas the article was not an effective treatment for fits. The article was misbranded while held for sale after shipment in interstate commerce.

Urinary antiseptic tablets. Misbranding, Section 502 (a), certain statements on the box label of the article and in the accompanying folder were false and misleading since the statements represented and suggested that the article was an effective treatment for urinary disturbances and certain urinary infections, whereas there are urinary disturbances and certain urinary infections for which the article would be of no value; and its labeling failed to reveal those disturbances and infections for which the article might be expected to be of some value as a urinary antiseptic. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warning against unsafe dosage and duration of administration since it failed to warn that relatively small amounts of methenamine are capable of causing kidney disease in dogs. The article was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: November 27, 1951. Ranger Products Co., Inc., New Haven, Conn., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for relabeling under the supervision of the Fedeal Security Agency.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3641–3660

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *May 20, 1952.*

CONTENTS*

*For presence of a habit-forming narcotic without warning statement, see Nos. 3642, 3643, 3646, 3647; omission of, or unsatisfactory, ingredients statements, Nos. 3642, 3643, 3646, 3647, 3650; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3642–3648; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3645.

999079—52——1

DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3641. Misbranding of Gattis worm oil. U. S. v. 9 Cases * * *. (F. D. C. No. 29057. Sample No. 82206–K.)

LIBEL FILED: On or about April 13, 1950, Southern District of West Virginia.

ALLEGED SHIPMENT: On or about March 10, 1950, by the Gattis Chemical Co., from Nashville, Tenn.

PRODUCT: 9 cases, each containing 12 1-ounce bottles, of *Gattis worm oil* at Williamson, W. Va.

LABEL, IN PART: "Gattis' Worm Oil Each Fluid Ounce Contains: 22 Mins. Oil Worm Seed, 12 Mins. Chloroform, 421 Mins. Castor Oil, Turpentine, Combined with Aromatics. Directions: Children 2 to 5 years old, one-half teaspoonful; 5 to 10 years old, one teaspoonful. Adults, one and a half teaspoonfuls. One dose morning and night; (May be given for 2 or 3 days if necessary.)."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: May 8, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3642. Misbranding of pentobarbital sodium capsules, Seconal Sodium capsules, sulfadiazine tablets, and racemic amphetamine sulfate (Benzedrine Sulfate) tablets. U. S. v. Edmond V. Bragard (Bragard Pharmacy). Plea of guilty. Defendant placed on probation for 2 years. (F. D. C. No. 31275. Sample Nos. 79358–K, 79361–K, 79369–K, 79373–K, 79376–K, 79395–K, 79399–K, 80426–K, 80427–K, 80447–K, 80574–K, 80578–K, 80583–K, 80587–K.)

INFORMATION FILED: December 10, 1951, District of Rhode Island, against Edmond V. Bragard, trading as Bragard Pharmacy, Woonsocket, R. I.

INTERSTATE SHIPMENT: From the States of Massachusetts, Indiana, and Pennsylvania, into the State of Rhode Island, of quantities of *pentobarbital sodium capsules, Second Sodium capsules, sulfadiazine tablets,* and *racemic amphetamine sulfate (Benzedrine Sulfate) tablets.*

ALLEGED VIOLATION: On or about September 2, 1949, and August 8, 24, and 31, September 18, October 17, 23, 24, 30, and 31, and November 3, 8, and 9, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged *pentobarbital sodium capsules, Seconal Sodium capsules,* and *racemic amphetamine sulfate (Benzedrine Sulfate) tablets* failed to bear adequate directions for use;

and Section 502 (e) (1), the labels of the repackaged *racemic amphetamine sulfate tablets* and the *sulfadiazine tablets* failed to bear the common or usual name of the drug.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* and the *pentobarbital sodium capsules* contained derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels on the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear adequate warnings against use in those pathological conditions where the use of the drug may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 18, 1951. A plea of guilty having been entered, the court placed the defendant on probation for 2 years.

3643. Misbranding of pentobarbital sodium capsules, Dexedrine Sulfate tablets, and sulfadiazine tablets. U. S. v. Bond Drug Store, Harold G. Griffin, and Robert V. West. Pleas of guilty. Fine of $135, plus costs, against individuals jointly. No fine imposed against partnership. (F. D. C. No. 30567. Sample Nos. 76956-K, 76964-K, 76977-K, 76978-K, 77147-K, 77772-K, 78216-K, 78218-K.)

INFORMATION FILED: April 26, 1951, Western District of Missouri, against the Bond Drug Store, a partnership, Lebanon, Mo., and Harold G. Griffin, a partner in the partnership, and Robert V. West, a pharmacist for the partnership.

INTERSTATE SHIPMENT: From the States of Illinois, Indiana, and Pennsylvania, into the State of Missouri, of quantities of *pentobarbital sodium capsules*, *Dexedrine Sulfate tablets*, and *sulfadiazine tablets*.

ALLEGED VIOLATION: On or about May 21, June 12 and 17, and July 5, 6, and 12, 1950, while the drugs were being held for sale at the Bond Drug Store after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

The Bond Drug Store and Harold G. Griffin were charged with causing the acts of repacking and sale of the drugs involved in each of the 8 counts of the information, and, in addition, Robert V. West was charged in 2 of the counts with causing such acts to be done in connection with the drug involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further, misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* and the *sulfadiazine tablets* failed to bear labels containing the common

or usual name of the drugs; Section 502 (f) (1), the repackaged *pentobarbital sodium capsules* and the *Dexedrine Sulfate tablets* failed to bear labeling containing adequate directions for use since the directions "1 capsule at bedtime when needed" and "one at bedtime as needed," borne on the labeling of the repackaged *pentobarbital sodium capsules*, and the directions "2 tablets each morning," borne on the labeling of the repackaged *Dexedrine Sulfate tablets*, were not adequate directions for use; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 7, 1951. Pleas of guilty having been entered, the court imposed a fine of $135, plus costs, against the individual defendants jointly. No fine was imposed against the partnership.

3644. Misbranding of dextro-amphetamine sulfate (Dexedrine Sulfate) tablets. U. S. v. Physicians & Surgeons Apothecary & Surgical Supply Co., Inc., and Sam O'Neal and Sam S. Romano. Pleas of nolo contendere. Corporation fined $150; each individual defendant fined $50. (F. D. C. No. 31289. Sample Nos. 21411–L, 21414–L, 21423–L.)

INFORMATION FILED: December 21, 1951, Northern District of Alabama, against Physicians & Surgeons Apothecary & Surgical Supply Co., Inc., Birmingham, Ala., and Sam O'Neal, vice-president of the corporation, and Sam S. Romano, treasurer.

ALLEGED SHIPMENT: From the State of Pennsylvania into the State of Alabama, of quantities of *dextro-amphetamine sulfate* (*Dexedrine Sulfate*) *tablets*.

ALLEGED VIOLATION: On or about May 1, 2, and 5, 1951, while the drug was being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drug to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents since the label bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use since the labeling bore no directions for use.

DISPOSITION: January 10, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $150 against the corporation and $50 against each individual defendant.

3645. Misbranding of dextro-amphetamine sulfate (Dexedrine Sulfate) tablets. U. S. v. Goldstein's Pharmacy, Phillip Goldstein, and Sidney Schatz. Pleas of nolo contendere. Partnership fined $150; each individual defendant fined $50. (F. D. C. No. 31290. Sample Nos. 55077–K, 20751–L, 20767–L, 21415–L, 21427–L.)

INFORMATION FILED: December 18, 1951, Northern District of Alabama, against Goldstein's Pharmacy, a partnership, Ensley, Ala., and Phillip Goldstein, a partner, and Sidney Schatz, a pharmacist.

ALLEGED SHIPMENT: From the State of Pennsylvania into the State of Alabama, of quantities of *dextro-amphetamine sulfate* (*Dexedrine Sulfate*) *tablets*.

ALLEGED VIOLATION: On or about December 18, 1950, and January 8, March 6, and May 2 and 7, 1951, while the drug was being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drug to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear labels containing a statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use; and Section 502 (b) (1), portions of the repackaged drug failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: January 10, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $150 against the partnership and $50 against each individual defendant.

3646. Misbranding of Dexedrine Sulfate tablets and Seconal Sodium capsules. U. S. v. Chester A. Baker, Inc., and Julian Felloni. Pleas of nolo contendere. Corporation fined $250; individual defendant fined $50. (F. D. C. No. 30623. Sample Nos. 48190-K, 62850-K, 62852-K, 62853-K, 62856-K, 79705-K, 80272-K, 80320-K, 80367-K.)

INFORMATION FILED: November 8, 1951, District of Massachusetts, against Chester A. Baker, Inc., Boston, Mass., and Julian Felloni, manager.

INTERSTATE SHIPMENT: From the States of Pennsylvania and Indiana into the State of Massachusetts, of quantities of *Dexedrine Sulfate tablets* and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about September 18, 19, 25, and 26, and October 3, 5, 6, and 10, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded. The corporation was charged with causing the acts of repacking and sale of the drugs involved in the 9 counts of the information, and Julian Felloni was charged likewise in 5 of the counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use; and Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* were not designated by a name recognized in an official compendium, and the labels failed to bear the common or usual name of the drug.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: December 7, 1951. Pleas of nolo contendere having been entered the court imposed a fine of $250 against the corporation and $50 against the individual defendant.

3647. Misbranding of Tuinal capsules, Gantrisin tablets, and Benzedrine Sulfate tablets. U. S. v. Nathan Stoller (Stoller's Pharmacy). Plea of nolo contendere. Fine, $300. (F. D. C. No. 31243. Sample Nos. 79980–K, 80009–K to 80012–K, incl., 80244–K to 80251–K, incl.)

INFORMATION FILED: November 8, 1951, District of Massachusetts, against Nathan Stoller, trading as Stoller's Pharmacy, Boston, Mass.

INTERSTATE SHIPMENT: From the States of Massachusetts, New Jersey, Indiana, and Pennsylvania, into the State of Massachusetts, of quantities of *Tuinal capsules*, *Gantrisin tablets*, and *Benzedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about August 26 and 28 and September 1, 7, 10, 11, 13, and 18, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *Tuinal capsules* contained derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the capsules failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the labels of the *Benzedrine Sulfate tablets* failed to bear the common or usual name of the drug; Section 502 (e) (2), the *Gantrisin tablets* were fabricated from two or more ingredients, and the labels of the tablets failed to bear the common or usual name of each active ingredient of the drug; and, Section 502 (f) (2), the labeling of the repackaged *Gantrisin tablets* failed to bear adequate warnings against use in those pathological conditions where the use of the drug may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: December 6, 1951. A plea of nolo contendere having been entered, the court imposed a fine of $300.

3648. Misbranding of thyroid tablets and diethylstilbestrol tablets. U. S. v. Ole R. Ronning (Ronning Drug Store). Plea of guilty. Fine, $200. (F. D. C. No. 30038. Sample Nos. 64644–K, 64656–K, 64668–K, 76128–K.)

INFORMATION FILED: March 29, 1951, District of South Dakota, against Ole R. Ronning, trading as Ronning Drug Store, Sioux Falls, S. Dak.

INTERSTATE SHIPMENT: From the States of Minnesota and Indiana into the State of South Dakota, of quantities of *thyroid tablets* and *diethylstilbestrol tablets*.

ALLEGED VIOLATION: On or about March 2 and April 12, 19, and 20, 1950, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents;

and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since it failed to bear any directions for use.

DISPOSITION: November 29, 1951. A plea of guilty having been entered, the court imposed a fine of $200.

3649. Alleged misbranding of fenugreek tea, Cetabs tablets, Ribotabs tablets, Niamin tablets, Ormotabs tablets, Kordel-A capsules, and Minerals Plus Chlorophyll and Vitamin D tablets. U. S. v. 269 Packages, etc. (and 1 other seizure action). (F. D. C. Nos. 19401, 19722. Sample Nos. 14049–H, 43774–H to 43778–H, incl., 43780–H.)

LIBELS FILED: March 13, 1946, Southern District of Ohio, and April 30, 1946, Southern District of California; amended libels filed in Southern District of Ohio on or about October 22, 1947, and in Southern District of California on or about January 19, 1948.

ALLEGED SHIPMENT: Between the approximate dates of January 1, 1945, and March 22, 1946, by Lelord Kordel Products and Nutrition Enterprises (national distributor of Lelord Kordel Products), from Chicago, Ill.

PRODUCT: 231 4-ounce packages, 36 1-pound packages, and 2 4-pound packages of *fenugreek tea* at Cincinnati, Ohio, and 118 30-tablet boxes of *Cetabs tablets*, 288 50-tablet boxes of *Ribotabs tablets*, 25 50-tablet boxes of *Niamin tablets*, 232 50-tablet boxes of *Ormotabs tablets*, 288 30-capsule boxes of *Kordel-A capsules*, and 432 100-tablet boxes of *Minerals Plus Chlorophyll and Vitamin D tablets* at Los Angeles, Calif.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the following conditions for which the articles were prescribed, recommended, and suggested in their advertising disseminated and sponsored by or on behalf of the manufacturer or packer:

Fenugreek tea. Removal from the body of dead cells; preventing formation of mucus and slime; preventing or treating inflammation and ulcers of the stomach and duodenum; torpid liver; diseased liver; inflammation of the colon or colitis; swelling of the legs; poor circulation of the blood; leucorrhea; mucous discharge from the head; boils; loss of smell; infection and rupturing of the appendix; peritonitis; overcoming obstacles to the proper absorption of food; and conditions interfering with the natural functions of the body;

Cetabs tablets. Treatment of allergies, aching joints, eczema, soft, bleeding, receding gums, flabby, soft tissues, red splotches of veins, tendency to bruise easily, and for keeping the cells of the body together;

Ribotabs tablets. Treatment or prevention of cataract of the eye, cracks in the tongue, corners of the eyes, finger tips, etc., itching of the lips and eyelids, and skin and eye conditions; effecting normal functioning and maintaining a healthy condition of the eyes; and maintaining maximum health;

Niamin tablets. Treatment or prevention of migraine headaches and high blood pressure accompanied by nervousness;

Ormotabs tablets. Regulating gland activity; producing hormones; benefitting the health and activity of glands; maintaining normal activity of the parathyroid gland; aiding the glands of the body; helping the glands to maintain body balance; assisting those approaching 40 and after 40; nourishing the glands of the body; helping the glands along; and causing the glands to function properly;

Kordel-A capsules. Treatment or prevention of certain infections, sinus trouble, poor complexion, poor vision, sensitiveness to glare, night blindness, red and swollen lids, squinting, and dryness of eyes; and

Minerals Plus Chlorophyll and Vitamin D tablets. Treatment or prevention of tumors, cysts, growths of various kinds, female troubles, and arthritis; keeping the brain in a healthier condition; maintaining health of the reproductive system; lengthening life; and prolonging youthful vitality.

Further misbranding, Section 502 (f) (1), the labeling of the articles, with the exception of the *fenugreek tea*, failed to bear adequate directions for use since the labeling failed to state any diseases or conditions for which the articles were to be used or taken.

The libel alleged also that another article, namely, Aminex amino acid tablets, was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Lelord Kordel appeared as claimant in the Ohio seizure and filed exceptions seeking dismissal of the libel against *fenugreek tea* and the Aminex amino acid tablets. A motion for discovery was filed subsequently by the claimant and was granted by the court in reference to the advertising, lectures, and records which the Government intended to rely upon in proving the conditions for which the *fenugreek tea* was intended to be used.

Lelord Kordel appeared also as claimant in the California seizure and filed exceptions to the libel, which were overruled on December 2, 1947. Subsequently, a motion to amend the libel was filed and granted. On March 1, 1948, pursuant to stipulation between the parties, the California seizure was transferred to the Southern District of Ohio and consolidated for trial with the Ohio seizure.

Thereafter, on February 18, 1952, upon stipulation between the parties that the cases presented no question for adjudication for the reason that all of the products under seizure had deteriorated and had become unmarketable, and with the consent of the parties and without any finding on any issue of fact or law, the court ordered that the products be destroyed.

3650. Adulteration and misbranding of Hexachlorophene-Special ointment and Hex-O-Phene ointment. U. S. v. 3 Drums, etc. (F. D. C. No. 31712. Sample No. 20822–L.)

LIBEL FILED: September 17, 1951, Northern District of Alabama.

ALLEGED SHIPMENT: On or about March 26, 1951, by W. F. Zimmerman, Inc., from Newark, N. J.

PRODUCT: 2 unopened drums, 1 partially filled drum, and 3¼ gross jars of ointment at Birmingham, Ala., in possession of the Wright Pharamacal Co., together with a number of circulars entitled "New Wonder Drug Discovered." The product contained in the drums had been invoiced *Hexachlorophene-Special ointment*, and that portion which was contained in the jars had been repackaged from one of the drums and labeled *Hex–O–Phene ointment*.

Analysis of the product showed that it contained not more than 1.06 percent of hexachlorophene.

RESULTS OF INVESTIGATION: The jars had been packed from one of the drums and labeled by the consignee. The circulars were being enclosed in packages with the jars, which were shipped to retailers.

LABEL, IN PART: (Drum) "To Wright Pharmacal Co. * * * Birmingham, Ala."; (jar) "Hex-O-Phene Ointment Contains: Hexachlorophene 2% in Zinc Oxide and Lanolin base."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 2% hexachlorophene.

Misbranding, Section 502 (e), the article was a drug fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), its labeling failed to bear adequate directions for use. The article was misbranded in the above respects when introduced into and while in interstate commerce. Further misbranding, Section 502 (a), certain statements on the jar label and in the circular entitled "New Wonder Drug Discovered" were false and misleading. These statements represented and suggested that the article was an adequate and effective treatment for burns, sores, impetigo, eczema, facial blemishes, and acne; that it would insure one freedom from infections; that it would keep skin germfree; that it would clear up a host of skin infections which have refused to yield to any previous treatments; and that it would keep one germfree and surgically clean. The article was not an adequate and effective treatment for such conditions, and it would not fulfill the promises of benefit made for it. The article was misbranded in the latter respects while held for sale after shipment in interstate commerce.

DISPOSITION: January 7, 1952. Default decree of condemnation. The court ordered that the product be delivered to a hospital or charitable institution.

3651. Misbranding of Rattlesnake Bill's Liniment. U. S. v. 129 Bottles * * *. (F. D. C. No. 31985. Sample No. 25709–L.)

LIBEL FILED: November 1, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 23, 1951, by the Frank Medicine Co., from Philadelphia, Pa.

PRODUCT: 129 bottles of *Rattlesnake Bill's Liniment* at Cowtown, N. J.

LABEL, IN PART: (Bottle) "Rattlesnake Bill's Liniment * * * Contents 2 Ounces Ingredients: Methyl salicylate; snake fat; gum camphor; kerosene; oil thyme; oil sassafras, artificial; oil mustard, synthetic; oil eucalyptus."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the product failed to bear adequate directions for use.

DISPOSITION: December 20, 1951. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3652. Adulteration and alleged misbranding of Estrocrine tablets. U. S. v. Woodard Laboratories, Inc., and Dean D. Murphy and John L. Sullivan. Pleas of not guilty. Tried to the court. Verdict of guilty on counts charging adulteration and not guilty on counts charging misbranding. Corporation fined $2,500; each individual defendant fined $250. (F. D. C. No. 30053. Sample Nos. 29794–K, 49677–K, 49693–K, 53254–K, 88164–K.)

INFORMATION FILED: May 8, 1951, Southern District of California, against Woodard Laboratories, Inc., Los Angeles, Calif., and Dean D. Murphy, president of the corporation, and John L. Sullivan, secretary and manager.

*See also Nos. 3650; veterinary preparation, 3659.

ALLEGED SHIPMENT: Between the approximate dates of July 12, 1949, and May 25, 1950, from the State of California into the States of Colorado and Texas.

LABEL, IN PART: "Prophylaxis W Therapeusis Woodard Laboratories, Inc. Estrocrine Tablets Each tablet contains: 0.022 mg. alpha estradiol."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since each tablet of the article was represented to contain 0.022 mg. of alpha-estradiol, whereas each tablet contained less than that amount of alpha-estradiol.

Misbranding, Section 502 (a), the label statement "Each tablet contains: 0.022 mg. alpha estradiol" was false and misleading as applied to an article which did not contain 0.022 mg. of alpha-estradiol per tablet, but contained less than that amount.

DISPOSITION: Pleas of not guilty having been entered, the case came on for trial before the court on November 7, 1951. On November 8, 1951, the court handed down a verdict of guilty as to all of the defendants on counts 1, 3, 5, 7, and 9, involving charges of adulteration, and a verdict of not guilty as to counts 2, 4, 6, 8, and 10, involving charges of misbranding. On December 3. 1951, the court imposed a fine of $2,500 against the corporation and $250 against each individual defendant.

3653. Alleged adulteration and misbranding of Fer Heparum B_{12}. U. S. v. Torigian Laboratories, Inc., and John Torigian. Plea of not guilty. Tried to the court and jury. Verdict of not guilty. (F. D. C. No. 28127. Sample Nos. 47817-K, 56567-K.)

INDICTMENT RETURNED: May 31, 1951, Eastern District of New York, against Torigian Laboratories, Inc., Queens Village, New York, N. Y., and John Torigian, president of the corporation.

ALLEGED SHIPMENT: On or about August 10 and October 28, 1948, from the State of New York into the District of Columbia and the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (c), the indictment alleged that the purity and quality of the article fell below that which it purported and was represented to possess since it purported and was represented to be suitable and appropriate for intramuscular injection, which use requires a sterile product, whereas the article was not suitable and appropriate for intramuscular injection since it was not sterile but was contaminated with viable microorganisms.

Misbranding, Section 502 (a), the indictment alleged that the label statement "For Intramuscular Injection" which was displayed upon the boxes containing the article and the label statement "Intramuscular" which was displayed upon the ampuls were false and misleading.

DISPOSITION: Pleas of not guilty having been entered, the matter came on for trial before the court and jury on November 26, 1951. On November 29, 1951, the jury rendered a verdict of not guilty.

3654. Adulteration of dl-amphetamine sulfate, dextro-amphetamine phosphate, dextro-amphetamine sulfate, and dextro-amphetamine base. U. S. v. Tru-Synthetics, Inc. Plea of guilty. Fine, $1,200. (F. D. C. No. 30050. Sample Nos. 42999–K, 73632–K, 73633–K, 73635–K, 81202–K, 81205–K.)

INFORMATION FILED: March 26, 1951, Eastern District of New York, against Tru-Synthetics, Inc., Long Island City, N. Y.

ALLEGED SHIPMENT: On or about October 7, 1949, and April 21, and May 8, 16, and 26, 1950, from the State of New York into the States of Illinois, New Jersey, and Pennsylvania.

LABEL, IN PART: "Manufacturers Tru-Synthetics, Inc. Long Island City 1, N. Y. * * * dl-Amphetamine Sulfate * * * For Manufacturing Use Only," "Dextro-Amphetamine Phosphate," "Dextro-Amphetamine Sulfate," and "Dextro-Amphetamine Base."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the drugs differed from, and their quality fell below, that which they were represented to possess since the *dl-amphetamine sulfate* contained more laevo-amphetamine sulfate than dextro-amphetamine sulfate, whereas *dl-amphetamine sulfate* is composed of equal proportions of dextro-amphetamine sulfate and laevo-amphetamine sulfate; the *dextro-amphetamine phosphate* contained laevo-amphetamine phosphate in addition to dextro-amphetamine phosphate; the *dextro-amphetamine sulfate* contained laevo-amphetamine sulfate in addition to dextro-amphetamine sulfate; and the *dextro-amphetamine base* contained laevo-amphetamine in addition to dextro-amphetamine.

Further adulteration, Section 501 (d) (2), the substances referred to above had been substituted for *dl-amphetamine sulfate*, *dextro-amphetamine phosphate*, *dextro-amphetamine sulfate*, and *dextro-amphetamine base*.

DISPOSITION: November 29, 1951. A plea of guilty having been entered, the court imposed a fine of $1,200.

3655. Adulteration and misbranding of rubber prophylactics. U. S. v. 93 Gross * * *. (F. D. C. No. 28864. Sample No. 64751–K.)

LIBEL FILED: On or about February 20, 1950, District of Minnesota.

ALLEGED SHIPMENT: On or about January 3 and 13, 1950, by the Dean Rubber Mfg. Co. from North Kansas City, Mo.

PRODUCT: 93 gross of *rubber prophylactics* at Minneapolis, Minn. Examination of samples showed that 3.23 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks Reservoir Ends."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "For Your Protection—An Aid in Preventing Venereal Diseases" were false and misleading as applied to the article since it contained holes.

DISPOSITION: December, 18, 1951. The Dean Rubber Mfg. Co. having filed a claim of ownership, but having made no answer or appearance other than such claim, the court, upon motion of the Government, heard the evidence adduced on behalf of the Government. The court found that the article was adulterated and misbranded as charged and ordered that it be destroyed.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3656. Alleged misbranding of Oracort. U. S. v. Herman Edward Maurry (H. E. Maurry Biological Co.). Plea of not guilty. Tried to the court and jury. Verdict of not guilty. (F. D. C. No. 30014. Sample Nos. 71400–K, 72461–K.)

INFORMATION FILED: March 1, 1951, Southern District of California, against Herman Edward Maurry, trading as the H. E. Maurry Biological Co., Los Angeles, Calif.

ALLEGED SHIPMENT: On or about December 20, 1949, and within the period from on or about September 19, 1949, to on or about December 30, 1949, from the State of California into the States of Arizona and Indiana.

NATURE OF CHARGE: Alleged misbranding, Section 502 (a), certain statements in accompanying blotters entitled "Oracort," pamphlets entitled "Oracort Biologically Standardized Oral Suprarenal Cortex Hormones," and a mimeographed sheet dated November 18, 1949, were false and misleading. These statements represented, suggested, and created the impression that the article would be efficacious in the treatment of arthritis and that it contained a therapeutically significant amount of cortisone, whereas the article was not effective in the treatment of arthritis, and it did not contain a therapeutically significant amount of cortisone.

DISPOSITION: A plea of not guilty having been entered, the matter came on for trial before the court and jury on December 18, 1951. On December 20, 1951, the jury rendered a verdict of not guilty.

3657. Misbranding of Murtex. U. S. v. 4,500 Cartons * * *. (F. D. C. No. 31148. Sample No. 9092–L.)

LIBEL FILED: May 25, 1951, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 1, 1950, from New York, N. Y.

PRODUCT: 4,500 cartons, each containing 1 bottle of *Murtex*, at Chicago, Ill., in possession of the Martax Botanical Corp.

RESULTS OF INVESTIGATION: The drug was shipped in a 50-gallon drum and was bottled and labeled for the Martax Botanical Corp. after shipment in interstate commerce. Each bottle was packed in a carton, together with a leaflet entitled "Murtex."

LABEL, IN PART: (Carton) "Murtex A Diuretic and Stimulant to the Kidneys. * * * (One fluid Oz.) Alcohol 40% By Volume Contains Fluid Extracts of: Buchu Cimicifuga Collinsonia Guaiacum Also Contains: 60 Mgs. Vitamin B_1 (Thiamine HCL) to each 30 cc."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets were false and misleading since these statements represented and suggested that the article was effective to eliminate from the body waste substances that cause the pain of arthritis and rheumatism, loss of energy and appetite, and simple nervousness and sleeplessness, whereas the article was not effective for such purposes. The article was misbranded while held for sale after shipment in interstate commerce.

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*See also Nos. 3650, 3652, 3653, 3655.

DISPOSITION: October 5, 1951. The Martax Botanical Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the article be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency.

3658. Misbranding of blackstrap molasses. U. S. v. 8 Cartons, etc. Amended libel filed following decision of court that original libel be dismissed. Decree of condemnation. (F. D. C. No. 30780. Sample No. 6754–L.)

LIBEL FILED: March 2, 1951, Western District of New York; amended libel filed May 10, 1951.

ALLEGED SHIPMENT: On or about November 30 and December 7, 14, and 21, 1950, and January 11, 1951, by Nature Food Centres, from Boston, Mass.

PRODUCT: 8 cartons, each containing 24 1-pint jars, and 8 cartons, each containing 12 1-quart jars, of *blackstrap molasses* at Rochester, N. Y., in possession of Nature Food Centres, together with a number of copies of a book entitled "Look Younger Live Longer," by Gayelord Hauser, which related to the product.

LABEL, IN PART: (Jar) "Plantation 'The Original' Recommended and Endorsed by Gayelord Hauser Blackstrap Molasses (Crude Black Molasses) * * * Packed by Allied Molasses Co., Inc., Perth Amboy, N. J."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the book entitled "Look Younger Live Longer," by Gayelord Hauser, which accompanied the article, contained statements which were false and misleading. The statements represented and suggested that the article would add five youthful years to an individual's life and was an excellent source of many B vitamins; that it was effective in the treatment of deficiencies of B vitamins, in the prevention and treatment of menopausal difficulties and menstrual abnormalities, and in inducing sleep; that it was effective to prevent and correct nervousness, to grow hair and correct baldness, and to restore gray hair and to restore it to its natural color; that it was effective to promote better digestion, healthy nerves, and healthy heart; that it was effective to prevent and correct constipation, poor digestion, tiredness, heart trouble, neuritis, and gas; that it was effective to prevent changes due to old age; and that it was effective to promote normal functioning of the glands. The article was not capable of fulfilling the promises of benefit made for it, and it was not effective for the purposes stated and implied.

The article was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: Farrar, Straus & Young, Inc., New York, N. Y., appeared as claimant for the books and moved for an order dismissing the libel insofar as it related to the seized copies of the book. On April 14, 1951, after consideration of the arguments and briefs of counsel, the court handed down the following opinion sustaining the claimant's motion:

BURKE, *District Judge*: "The government filed a libel of information asking seizure and condemnation under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 301 et seq. of a certain quantity of 'Plantation' blackstrap molasses, packed by Allied Molasses Co., Inc., and certain copies of a book entitled 'Look Younger, Live Longer' by Gayelord Hauser. The libel alleges in substance

that the 'Plantation' molasses and copies of the book 'Look Younger, Live Longer' were shipped via the same carrier on or about November 30, December 7, 14 and 21, 1950, and January 11, 1951, from Nature Food Centres, Inc., Boston, Massachusetts, to Rochester, New York, and that the molasses was misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce, within the meaning of Sections 343 (a) and 352 (a) of Title 21 U. S. C. in that the book accompanied the molasses and thus constituted false and misleading labeling. A quantity of the molasses and a number of copies of the book were seized by the United States Marshal at a retail store owned and operated by Rochester Natural Food Store, Inc., on March 6, 1951, under a warrant issued by this court pursuant to the libel.

"Farrar, Straus and Young, Inc., has filed a claim to the seized copies of the book alleging that it is the publisher and bona fide owner of the books. It moves here for an order, pursuant to Rule 12 (b) (6) of the Federal Rules of Civil Procedure, dismissing the libel in so far as it relates to the seized copies of the book, on the ground that the libel in so far as it relates to the books, fails to state a claim upon which relief can be granted under the Act in that book did not and does not constitute 'labeling,' within the meaning of the Act.

"The seizure was based upon Section 334 (a) of Title 21 U. S. C. which provides:

> Any article of food, drug, * * * that is * * * misbranded when introduced into or while in interstate commerce or while held for sale * * * after shipment in interstate commerce, * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: * * *.

"The claim that the molasses was misbranded is based on the ground that the book constituted 'labeling.' This is based on the assertion that copies of the book and a quantity of the molasses were shipped simultaneously from a Boston wholesaler to Rochester via the same carrier, and thus that the statements of the author contained in the book regarding blackstrap molasses accompanied the molasses so as to constitute the book 'labeling' of the product, and that such statements are false and misleading since the article is not capable of fulfilling the promises of benefit made for it and is not effective for the purposes stated or implied.

"Molasses is a dark colored viscid syrup which drains from sugar in the process of manufacture. The seizure involved molasses packed for sale in pint and quart jars. The pint jars had a selling price of 29¢, the quart jars 49¢.

" 'Look Younger, Live Longer' is a full-length book containing 383 pages. It was first published in February, 1950. It has had 16 printings, totaling 340,000 copies. It is currently on the best seller list and has been since February, 1950. It has had a wide distribution and sale in book stores, department stores, health food stores and numerous other retail outlets. The book discusses the merits and uses of many foods, drugs, and cosmetics generally, including blackstrap molasses. It does not mention 'Plantation' blackstrap molasses or any other food, drug, device or cosmetic by trade mark or brand name. It advertises no products. The publisher is engaged solely in the business of publishing books. It has no connection with any manufacturer, processor, packer or seller of food, nor does the libel make any claim that it has, other than such as might be implied from the claim that the statements contained in the book regarding the blackstrap molasses constituted 'labeling' of the product.

"The motion involves the interpretation of the meaning of 'labeling' as used in the Act. Section 343 (a) provides that a food shall be deemed to be misbranded if its 'labeling' is false or misleading in any particular. Section 321 (m) defines 'labeling' to mean '* * * all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.'

"The circumstance of simultaneous shipment of written, printed, or graphic matter with an article of food, or drug via the same carrier, without more, does not constitute the written, printed, or graphic matter 'labeling' of the product. It must have some relation to the food or drug. Otherwise an allegation of

mere physical accompaniment in an interstate shipment would be enough to draw into the condemnation of the statute written, printed, or graphic matter wholly unrelated to the article claimed to be misbranded. Nor is the circumstance that written, printed, or graphic matter alleged to be 'labeling,' did not physically accompany the article in shipment, sufficient to establish that it is not 'labeling,' within the meaning of the Act, so long as 'they were parts of an integrated distribution program.' Kordel vs. United States, 335 U. S. 345, 350.

" 'Look Younger, Live Longer' is a publication entirely independent in authorship and unrelated to the enterprise of marketing 'plantation' blackstrap molasses. It had attained wide acceptance as a publication long before the alleged violation in question. It had been generally sold in retail stores where books are usually sold. It was a legitimate publication for bona fide sale even in a food store. There is no claim in the libel that the selling price of $3 per copy was a fictitious selling price nor any claim that a purchaser of 'Plantation' blackstrap molasses could get it for less than $3 per copy with a purchase of a pint jar for 29¢ or a quart jar for 49¢. It was not an 'easy device of a "sale" of the advertising' to circumvent the Act as in Kordel. (Page 305).

"But, the government says, the allegations of the libel must be accepted as true for purposes of this motion and so, counsel argues, the allegation that the book served to misbrand the article while it was being held for sale after shipment in interstate commerce, must be accepted as true. That allegation is nothing more than a legal conclusion. The question presented here is whether the allegations of fact, not legal conclusions, are sufficient to support the seizure. The question whether the use to which the book was put in connection with marketing the molasses, while held for sale after shipment, constitutes 'labeling' is not here for determination, because the libel contains no allegations respecting such use. The seizure of the books rests on the naked claim that the molasses was misbranded because it was simultaneously shipped with the books in interstate commerce via the same carrier.

"There are no allegations of fact in the libel amounting to functional interdependence of the article and the books, so as to constitute the books 'labeling' under the Act.

"The libel in so far as it relates to the book 'Look Younger, Live Longer' should be dismissed and the seizure of the books vacated."

On April 23, 1951, a notice of motion to amend the libel was filed on behalf of the Government; thereafter, a motion to amend was filed, together with the briefs of the parties; and on May 10, 1951, the court ordered that the Government's motion for leave to file an amended libel of information be granted.

The amended libel alleged further that the book entitled "Look Younger, Live Longer" by Gayelord Hauser accompanied the article as labeling when it was introduced into, while in, and while held for sale after shipment in, interstate commerce by reason of the following:

The labels on the jars of the article contained no reference to any disease or condition of the body, or to the vitamin or mineral content of the article, except that the statement "The mineral content is high" appeared on the label.

The labels on the jars of the article bore on the principal panel the legend "Recommended and Endorsed by Gayelord Hauser."

The author of the book "Look Younger, Live Longer" is the said Gayelord Hauser.

The book by Gayelord Hauser contained recommendations and endorsements for *blackstrap molasses* in the treatment of diseases and conditions of the body and as to the vitamin and mineral content of *blackstrap molasses*.

That "Plantation Blackstrap Molasses" was the only *blackstrap molasses* recommended and endorsed by Gayelord Hauser; and *blackstrap molasses* differs from the usual or customary article of food sold as "molasses" in that it is "The poorest, is the final, or exhausted molasses of raw sugar manufacture"

(The Encyclopedia of Food, Artemas Ward, 1941), and is defined in Cane Sugar Handbook, Spencer and Meade, 1945, as—

> Refining Sirup, Barrel Sirup. Refining Blackstrap. The end product of the refinery is the sirup purged from the lowest-grade remelt strikes which have been cured in crystallizers. In those plants which do not char-filter their low-grade materials, this product is refinery blackstrap and does not differ materially from cane factory blackstrap, although it is usually less viscous. It is used for the same purposes, viz., alcohol manufacture, cattle feed yeast.

That by reason of such recommendation and endorsement, Gayelord Hauser benefited, was benefiting, and would continue to benefit by the sale of "Plantation Blackstrap Molasses," in that, by the terms of an agreement with the Allied Molasses Co., Inc., the packer of said "Plantation Blackstrap Molasses," a so-called royalty or remuneration was set aside for the benefit of the said Gayelord Hauser, based on the output of such product bearing his endorsement and recommendation.

In addition to the product and the book having a common origin at Boston, Mass., and a common destination at Rochester, N. Y., and accompanying each other in interstate commerce, there was transmitted also in interstate commerce, via the U. S. Mails, on or about January 13, 1951, from Nature Food Centres, Boston, Mass., to Nature Food Centres, Rochester, N. Y., a certain window display poster featuring (1) a reprint of an article by the said Gayelord Hauser which appeared in the January 1951 issue of Cosmopolitan Magazine, (2) a printed list which read, in part, as follows:

> Hauser Dieters, Now You Can order all products for the Hauser diet and Gayelord Hauser books by mail * * * Plantation Blackstrap Molasses 33¢ Nature Food Centres

and (3), in handwriting, "We have all foods and books for the Hauser diet! Come in for full information."

The book and poster were displayed prominently in the store window of Nature Food Centres at Rochester, N. Y., together with a number of jars of "Plantation Blackstrap Molasses."

In response to the invitation to "Come in for full information" with respect to products for the Hauser diet and the Gayelord Hauser books, the customary practice was to hand a prospective purchaser of "Plantation Blackstrap Molasses" a copy of the book "Look Younger, Live Longer," and referring the purchaser to the index of this book wherein references are made to those pages which pertain to the uses and purposes of *blackstrap molasses.* The uses and purposes of *blackstrap molasses* in the book referred to diseases and conditions of the body and the vitamin and mineral content of *blackstrap molasses.*

That by reason of the foregoing uses to which the book "Look Younger, Live Longer" was put and as part of the same interstate transaction and distributional scheme in connection with the marketing of "Plantation Blackstrap Molasses," the book constituted labeling for the article when the article was introduced into, while in, and while held for sale after shipment in, interstate commerce.

Following the filing of the amended libel, the claimant filed a motion to dismiss this libel insofar as it related to the seized copies of the book; and on August 2, 1951, the following decision was handed down by the court in denial of such motion:

BURKE, *District Judge*: "This is a motion by the claimant, the publisher of the book 'Look Younger, Live Longer' by Gayelord Hauser, and the owner of 25 copies of the book seized by the Government, to dismiss the amended libel in so far as it relates to the seized copies of the book, on the ground that the amended libel in so far as it relates to the books fails to state a claim upon which relief can be granted under the Federal Food, Drug and Cosmetic Act, 21 U. S. C. 301 et seq. The claim is that the book did not and does not constitute 'labeling' within the meaning of the Act. Heretofore, on April 14. 1951, on motion of the publisher, the original libel in so far as it related to the book 'Look Younger, Live Longer' was dismissed and the seizure of the books vacated.

"The amended libel alleges in part that the book contains statements which represent and suggest that the article (blackstrap molasses) will add five youthful years to an individual's life, is an excellent source of many B vitamins, is effective in the treatment of deficiencies of B vitamins, is effective in the prevention and treatment of menopausal difficulties and menstrual abnormalities, is effective in inducing sleep, is effective to prevent and correct nervousness, to grow hair and correct baldness, to restore gray hair and correct baldness, to restore gray hair to its natural color, is effective to promote better digestion, healthy nerves, healthy heart and to prevent and correct constipation, poor digestion, tiredness, heart trouble, neuritis and gas, is effective to prevent change due to old age, and is effective to promote functioning of the glands, all of which statements are claimed to be false and misleading since the article is not capable of fulfilling the promises of benefit made for it and is not effective for the purposes stated and implied. It alleges that the book accompanied the molasses as 'labeling' when the article was introduced into, while in, and while held for sale after shipment in interstate commerce. It alleges that on or about January 13, 1951, in a store conducted by Nature Food Centres at Rochester, New York, a window display featured a re-print of an article by the author of the book, Gayelord Hauser, which appeared in the January, 1951, issue of Cosmopolitan magazine, and a printed list which reads in part as follows:

> Hauser Dieters. Now you can order all products for the Hauser diet and Gayelord Hauser books by mail * * * "Plantation" Blackstrap Molasses 33¢, Nature Food Centres
>
> We have all foods and books for the Hauser diet. Come in for full information.

It alleges further that a copy of the book was prominently displayed in the store window of Nature Food Centres at 401 East Main Street, Rochester, New York together with a number of jars of 'Plantation' blackstrap molasses. It alleges further that in response to such invitation to 'come in for full information' that it was the customary practice to hand a prospective purchaser of 'Plantation' blackstrap molasses a copy of the book 'Look Younger, Live Longer,' by Gayelord Hauser, and to refer such prospective purchaser to the index of the book wherein references are made to those pages which pertain to the uses and purposes of blackstrap molasses. It alleges that by reason of the foregoing uses to which the book was put and as part of the same interstate transaction and distributional scheme in connection with the marketing of 'Plantation' blackstrap molasses, such book constituted 'labeling' for the article as defined in the Act, when the article was introduced into, while in, and while held for sale after shipment in interstate commerce.

"The publisher, concededly not a party to the plan of distribution and having no connection with Nature Food Centres in the marketing of molasses, claims that the Act provides no authority for the seizure and condemnation of its books as 'printed matter accompanying' an article. I can see no warrant in reason for such a narrow construction of Section 334 of the Act nor do I find any authoritative decisions indicating that the seizure provisions of the Act should be so circumscribed.

"The publisher further claims that to construe the publisher's book as 'labeling' of 'Plantation' blackstrap molasses would violate the publisher's right of freedom of the press under the Federal Constitution, and that this

summary seizure of copies of the book as 'labeling' of a commercial product violates the constitutional guarantee of freedom of the press. The Administrator by resorting to the seizure provisions of the Act does not undertake to interfere with the publication or circulation of the publisher's book. The seizure has not interfered with the bona fide sale of the book. The publisher may continue to sell its books wherever it finds a market, even in food stores, and even in stores where 'Plantation' blackstrap molasses is sold. The seizure relates not to books offered for bona fide sale but to copies of the book claimed to be offending against the Act by being associated with the article 'Plantation' Blackstrap Molasses in a distribution plan in such a way as to misbrand the product.

"Motion denied. It is hereby so ordered."

On September 10, 1951, the claimant having failed to pursue the matter further, judgment of condemnation was entered and the court ordered that the property, consisting of the molasses and the copies of the book under seizure, be distributed to various charitable organizations.

DRUGS FOR VETERINARY USE

3659. Adulteration and misbranding of Antihep tablets. U. S. v. 23 Bottles * * *. (F. D. C. No. 31946. Sample No. 3574–L.)

LIBEL FILED: On or about October 26, 1951, District of Maryland.

ALLEGED SHIPMENT: On or about August 13, 1951, by the Hopkins & Hopkins Pharmaceutical Co., from Philadelphia, Pa.

PRODUCT: 23 1,000-tablet bottles of *Antihep tablets* at Chestertown, Md. Analysis showed that the product contained not more than 1.23 grains of 2-amino-5-nitrothiazole per tablet.

LABEL, IN PART: (Bottle) "1000 Soluble Antihep Tablets Each Tablet Contains: 2 Grains 2-Amino-5-Nitrothiazole For Prevention and Control of Blackhead (enterohepatitis) in Turkeys."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, "2 Grains 2-Amino-5-Nitrothiazole."

Misbranding, Section 502 (a), the label statement "Each Tablet Contains: 2 Grains 2-Amino-5-Nitrothiazole" was false and misleading since the article contained less than 2 grains of 2-amino-5-nitrothiazole per tablet.

DISPOSITION: January 21, 1952. Hopkins & Hopkins Pharmaceutical Co., claimant, having admitted the allegations contained in the libel, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling in conformity with the law, under the supervision of the Federal Security Agency, conditioned that the product be delivered to a research institute for investigational use in the treatment of blackhead disease of turkeys.

3660. Misbranding of Hite's Super Culture. U. S. v. 24 Bags * * *. (F. D. C. No. 30825. Sample No. 18913–L.)

LIBEL FILED: February 15, 1951, District of Minnesota.

ALLEGED SHIPMENT: The drug was shipped on or about November 3, 1950, by the Super Culture Sales Co., manufacturer and seller of the drug, from Sioux City, Iowa. A number of circulars entitled 'Super Culture Feed" were delivered to the dealer on or about October 1, 1950, by Will Hite, one of the officers and stockholders of the manufacturer and seller.

PRODUCT: 24 bags, each containing 100 pounds, of *Hite's Super Culture* at Mapleton, Minn., together with a number of circulars entitled "Super Culture Feed."

LABEL, IN PART: "Hite's Super Culture * * * Ingredients – Yeast, Corn Oil Meal, Wheat Mids, Rye Mids, Oil Meal, Salt, Soda, Hylactic Yeast and Iron Oxide."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since these statements represented and suggested that the article was effective for the treatment of "necro" (necrotic enteritis) in pigs and hogs, whereas the article was not effective for the treatment of this condition.

DISPOSITION: September 15, 1951. Rolla E. Zimmerman, Mapleton, Minn., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3641 TO 3660

PRODUCTS

[1] (3658) Seizure contested. Contains opinions of the court.
[2] (3652, 3653, 3656) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3658) Seizure contested. Contains opinions of the court.
[2] (3652, 3653, 3656) Prosecution contested.

[2] (3652, 3653, 3656) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1952

D. D. N. J., F. D. C. 3661–3680 Issued June 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3661–3680

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *June 16, 1952.*

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*For presence of a habit-forming narcotic without warning statement, see No. 3665; omission of, or unsatisfactory, ingredients statements, Nos. 3665, 3675; failure to bear a label containing an accurate statement of the quantity of the contents, No. 3665; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3665.

205202—52——1

DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3661. Misbranding of male and female hormones. U. S. v. 628 Linguets, etc. (F. D. C. No. 31936. Sample Nos. 1039–L, 1040–L, 1062–L.)

LIBEL FILED: November 2, 1951, Southern District of Florida.

ALLEGED SHIPMENT: On or about June 25, 1951, and within the past 18 months from the date on which the libel was filed, from Cedar Rapids, Iowa.

PRODUCT: 628 5-milligram and 1,835 10-milligram *oral androgen male sex hormone linguets* and 887 *Vitro No. 318 oral estrogen female sex hormone linguets* at Jacksonville, Fla., in possession of the Vitro Co., together with a number of leaflets entitled "Oral Androgen Male Sex Hormones."

LABEL, IN PART: (Bottle) "Oral Androgen Male Sex Hormone Linguets for absorption through the oral mucous membranes 5 mg. [or "10 mg."]. Each linguet contains 5 mg. [or "10 mg."] of the pure methyl ester of testosterone, with more marked androgenic properties than testosterone when taken by mouth. Use as Directed by Your Physician. Distributed by the Vitro Company" and "Linguets Vitro No. 318 Oral Estrogen Female Sex Hormone Linguets for absorption through the oral mucous membranes. Each linguet contains naturally occurring estrogens, with estrons as the chief active principle, biologically standardized to the equivalent of 0.5 mg. estrogen=5000 I. U."

NATURE OF CHARGE: 5 and 10 milligram *oral androgen male sex hormone linguets.* Misbranding, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, namely, in the leaflet entitled "Oral Androgen Male Sex Hormone," as follows: "5 mg. to 40 mg. 3 times or more weekly before meals and preferentially in divided doses. Dosage should be lowered as improvement occurs to minimum maintenance levels." Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

Vitro No. 318 oral estrogen female sex hormone linguets. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where the use of the article may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: December 3, 1951. Default decree of condemnation and destruction.

3662. Misbranding of Detoxacolon (Hydr-Oxy-Colon) device. U. S. v. 1 Device * * * (F. D. C. 31715. Sample No. 30862–L.)

LIBEL FILED: June 19, 1951, Southern District of Illinois.

ALLEGED SHIPMENT: The product was ordered from, and invoiced by, the United X-Ray & Equipment Co., Los Angeles, Calif.; and various parts were shipped from Dallas, Tex., on or about June 23, 1950, and from Hollywood,

Calif., on or about June 22 and 29, 1950. There were also in possession of the consignee a copy of a booklet entitled "DeWelles Detoxacolon Oxygen Therapy" which had been received from a representative of the United X-Ray & Equipment Co. and a copy of a booklet entitled "Here's How Oxygen Can Put New Life Into Your Practice" which was received either directly or indirectly from a representative of the company.

PRODUCT: 1 *Detoxacolon (Hydr-Oxy-Colon) device* at Quincy, Ill., together with the 2 booklets referred to above.

LABEL, IN PART: (When shipped in interstate commerce) "Detoxacolon"; (after shipment in interstate commerce) "Hydr-Oxy-Colon Therapy Model 6 960 Serial Licensed under U. S. Patent No. 2420586."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklet entitled "DeWelles Detoxacolon Oxygen Therapy" were false and misleading. These statements represented and suggested that the device was an adequate and effective treatment for spasticity of the rectum, extreme ulceration of the lower bowel, common cold, sinusitis, dysentery, flaccid condition of the sphincters, ulcerative colitis, prolapse of the rectum and sigmoid, asthma, hay fever, acute coryza, ptosis of the colon, high blood pressure, low blood pressure, anemia, amebic dysentery, heart conditions, epilepsy, toxemias of pregnancy, and infections and inflammations of the female reproductive organs; that the device was an excellent treatment following childbirth to return muscle tone; and that it would correct any abnormal condition. The device was not an adequate and effective treatment for such disease conditions, and it was not capable of fulfilling such promises of benefit made for it.

Further misbranding, Section 502 (j), the device was dangerous to health when used with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, in the booklet entitled "DeWelles Detoxacolon Oxygen Therapy," since in the post partum period and in the acute stages of vaginal infections, treatment as directed would force infective material into or through the cervical canal, resulting in ascending infection with probable serious consequences to the health of the patient.

Further misbranding, Section 502 (a), certain statements in the booklet entitled "Here's How Oxygen Can Put New Life Into Your Practice" were false and misleading. These statements represented and suggested that the device was an adequate and effective treatment for many allergies, asthma, sinusitis, hay fever, arthritis, epilepsy, diabetes, neuritis, rheumatism, high and low blood pressure, pernicious and secondary anemias, certain varicoses, functional heart conditions, skin disorders, stomach ulcers, kidney conditions, parasites, rectal disorders, sluggish colon, infectious and inflammatory diseases of the female pelvis, colitis, and ulcerated colon; that it would kill certain infections and decay-producing causes; that it would control and regulate the activities of the brain, heart, circulation, and breathing; that it would aid digestion, assimilation, elimination, metabolism, gland functions, and acid-alkaline balance of the blood; that it would give a normal effect to the body in general; and that it would rebuild the bowels. The device was not an adequate and effective treatment for such diseases and conditions, and it was not capable of fulfilling the promises of benefit made for it.

The device was misbranded in the above respects when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: January 5, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3663. Action to enjoin and restrain the interstate shipment of various Alberty products. U. S. v. Alberty Food Products, et al. Tried to the court. Decree for injunction entered in district court. Judgment of district court affirmed on appeal to United States Court of Appeals. (Inj. No. 206.)

COMPLAINT FILED: September 16, 1949, Southern District of California, against Alberty Food Products, a partnership at Hollywood, Calif., also doing business under the name of Cheno Products, and against Ada J. Alberty and Kenneth Hackworth.

On October 7, 1949, an order was entered dismissing Kenneth Hackworth as a defendant; and, at the same time, an amended complaint was filed against Alberty Food Products, Ada J. Alberty, Harry Alberty, Florence Alberty, Margaret Quinn, and Helen Hackworth, as the individuals primarily responsible for the policies and activities of the partnership.

ALLEGED VIOLATION: The complaint alleged that the defendants were the manufacturers, packers, and distributors of certain drugs, namely, *Alberty's Vegetable Compound capsules, Alberty's Oxorin tablets, Alberty's Food Regular, Instant Alberty Food, Alberty Garlic perles (Alberty Garlic and Vegetable Oil perles), Alberty's Sabinol, Alberty Phloxo B tablets, Alberty's Phosphate pellets, Alberty's Riol tablets, Alberty's Rico tablets, Alberty Special Formula tablets, Alberty's vitamin A (high potency) shark liver oil, Alberty's Vi-C, wheat germ oil, Alberty's vitamin B complex tablets with high-potency B_1, Alberty's vitamin B_1 with supplementary amounts of other B complex factors, Alberty's Lebara pellets, plain, Alberty's Lebara pellets No. 2, Cheno herb tea, Cheno Phytolacca Berry Juice Extract tablets, Cheno combination tablets, Pandora tablets, Recal tablets, Alberty's Vio-Min vitamin-mineral tablets, Alberty's R-Gon tablets, Alberty's Laxative Blend Tea, Alberty's Ca-Mo pellets, Alberty's vitamin A and G perles,* and *Alberty's Rego.*

The drugs consisted for the most part of dried vegetables, cereals, vitamins, and minerals, in various combinations.

The complaint alleged further that the defendants had been and were continuing to introduce into interstate commerce the above-named drugs which were misbranded under Sections 502 (a) and 502 (f) (1); that the defendants had caused and were continuing to cause certain printed matter to accompany the drugs while held for sale after shipment in interstate commerce, which acts resulted in the drugs being misbranded under Section 502 (a); and that the defendants had caused and were continuing to cause certain oral representations to be made by demonstrators regarding the therapeutic effect of the drugs while held for sale after interstate shipment, which acts resulted in the drugs being misbranded under Section 502 (f) (1).

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying printed matter relating to the drugs were false and misleading since the drugs were not effective for the prevention, treatment, or cure of the diseases or conditions represented; and, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use for the purposes and conditions for which they were intended and for the purposes for which they were recommended by oral representations sponsored by the defendant.

*See also No. 3661.

The complaint alleged further, upon information and belief, that the defendants would continue to introduce the misbranded drugs into interstate commerce and would continue to do those acts while holding the drugs for sale after shipment in interstate commerce, which result in misbranding of the drugs.

DISPOSITION: The Government and the defendants having stipulated and agreed to certain facts in the case and the Government having filed a motion for summary judgment, the court, on June 8, 1951, handed down the following decision:

MATHES, *District Judge:* "The Government invokes the jurisdiction of this Court under § 302 (a) of the Federal Food, Drug and Cosmetic Act [52 Stat. 1043, 21 U. S. C. § 332 (a)] to enjoin alleged violations by defendants of § 301 which prohibits 'introduction * * * into interstate commerce of any * * * drug * * * that is * * * misbranded' [21 U. S. C. § 331 (a)].

"The amended complaint for injunction alleges *inter alia:*

That defendants are "the manufacturers, packers and distributors of certain articles of drug * * *";

That "For some years, defendants have introduced said articles of * * * drug into interstate commerce, and have caused said articles to be accompanied by various leaflets and booklets when introduced into and while in interstate commerce and while held for sale after shipment in interstate commerce. Said leaflets and booklets are entitled 'Calcium, The Staff of Life' [Exhibit 30]; 'Dynamic Digests' [Exhibit 31]; 'Is There Hope That Graying Hair Can Be Restored? Read What Science Says – Pandora' [Exhibit 32]; 'Health Mysteries' [Exhibit 33]; 'Reduce! Streamline Your Figure—Follow the 5 Factor Cheno Plan' [Exhibit 34]; 'Happy Figures by the Cheno Plan' [Exhibit 35]. Each of these booklets and leaflets relates to one or more of the above-mentioned articles of drug * * *";

That "At all times, the aforesaid articles of drug, when introduced into interstate commerce, have been and are now misbranded within the meaning of section 502 (f) (1) of the Act [21 U. S. C. § 352 (f) (1)], in that their labelings fail to bear adequate directions for use for the purposes and conditions for which they are intended."

At pretrial hearing the parties stipulated:

(1) That "defendants' products referred to in the Amended Complaint for Injunction are drugs and are shipped interstate by the defendants."

(2) That "Defendants ship all of their products in interstate commerce to health food retail outlets and intend to continue so shipping these products. Defendants also ship these products interstate direct to ultimate consumers in response to mail orders from such persons."

(3) That "Defendants are currently distributing [the above mentioned literature] interstate in the following ways * * *:

"(a) Defendants obtain the names and addresses of prospective customers from the retail outlets to which they sell their products. Defendants mail said literature to said prospective customers, and on such literature defendants print the name and address of the retail outlet that furnished such names and addresses.

"(b) Defendants also obtain the names and addresses of prospective customers from demonstrators who are hired by the defendants to work in retail outlets and there promote the sale of defendants' products. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer.

"(c) Defendants also obtain the names and addresses of prospective customers when individuals write in to the defendants for literature or

to submit mail orders. Defendants mail the aforesaid literature to said prospective customers, and on such literature defendants print the name and address of a retail outlet located in the same area as the prospective customer."

"Section 201 of the Act provides in part that:

(a) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement * * * that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper * * *.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers, or wrappers, or (2) accompanying such article.

"The parties have stipulated to the identity and content of the label used 'upon the immediate container' of each article, and further that such 'label' [21 U. S. C. § 321 (k), (1)] constitutes the entire 'labeling' [21 U. S. C. § 321 (m)] as to each article, unless the above-mentioned 'literature' is to be considered as 'accompanying such article' in interstate commerce within the meaning of § 201 (m) (2) of the Act [21 U. S. C. § 321 (m) (2)].

"Based upon the facts established by the pleadings and the pretrial stipulations, the Government has moved for summary judgment upon the ground: 'That there are no facts in dispute with respect to that portion of the Amended Complaint which seeks an injunction under 21 U. S. C. § 332 (a) to restrain defendants from violating 21 U. S. C. § 331 (a) through the continued interstate shipment of drugs that are misbranded in violation of 21 U. S. C. § 352 (f) (1),' which provides that: 'A drug * * * shall be deemed to be misbranded * * * (f) unless its labeling bears (1) adequate directions for use * * *.'

"In order to determine whether the labeling as to any 'drug' [21 U. S. C. § 321 (g)] bears 'adequate directions for use' within the meaning of the Act it is necessary of course first to ascertain what comprises 'its labeling.' Section 201 (m) declares that: 'The term "labeling" means all labels [see 21 U. S. C. § 321 (k), (1)] and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article' [21 U. S. C. § 321 (m)].

"In *Kordel* v. *United States*, 335 U. S. 345, 347, 348 (1948), where 'the literature involved * * * was shipped separately from the drugs and at different times' but 'had a common origin and a common destination,' the literature was held to accompany the drugs in interstate commerce within the meaning of the Act [21 U. S. C. § 321 (m)] and so to comprise a part of the 'labeling.' [See also *United States* v. *Urbuteit*, 335 U. S. 355 (1948); *United States* v. *Research Laboratories, Inc.*, 126 F. 2d 42, 45 (9th Cir. 1942).]

"As in the cases just cited, the literature involved at bar explains the claimed beneficial uses of each drug and was obviously 'designed for use in the distribution and sale'; while the 'label' itself is either totally or practically silent as to the purpose for which the drug is to be used; and usually, but not invariably, both the drug and the literature describing it have a common point of origin in interstate commerce. The point of difference in the case at bar is that generally speaking the article and the literature do not have a common destination, since defendants usually ship the drugs to a retail outlet, while the literature is shipped directly to prospective consumers.

"Thus the precise question on this phase of the case is whether the literature may properly be held to accompany the drug in interstate commerce within the meaning of 21 U. S. C. § 321 (m) (2), where the destination of the literature when shipped is not the distributor or consumer of the drug.

"The policy of the Act seems clearly to require that 'labeling' [21 U. S. C. § 321 (m)] which bears 'adequate directions for use' [21 U. S. C. § 352 (f) (1)] of the drug be placed 'upon the immediate container' [21 U. S. C. § 321 (k), (1)],

or accompany the container so closely that the ordinary consumer will be apprised of all directions, cautions and other information appearing thereon.

"Section 201 (k) provides that 'a requirement * * * that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper' [21 U. S. C. § 321 (k)].

"Section 201 (n) provides that: 'If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual' [21 U. S. C. § 321 (n)].

"And § 502 declares that: 'A drug or device shall be deemed to be misbranded—

> (a) If its labeling is false or misleading in any particular. * * *
>
> (c) If any word, statement, or other information required * * * to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. * * *
>
> (f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users. * * *
>
> (j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof. [21 U. S. C. § 352 (a), (c), (f), (j).]

"Nothing more than a reading together of these quoted provisions of the Act is required to demonstrate the emphasis placed by the Congress upon the contents of the labeling as a means of protecting the consumer, as well as the legislative intent that the labeling so closely accompany the drug into the hands of the consumer 'as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use' [21 U. S. C. § 352 (c); see *Alberty Food Products* v. *United States*, 185 F. 2d 321 (9th Cir. 1950)].

"Where, as here, the literature and drugs do not have a common destination and the literature is not shipped to either a distributor or a consumer of the drug, it would be in derogation of the policy and purposes of the Act to broaden further the content of the verb 'accompany' as employed in § 201 (m) (2), 21 U. S. C. § 321 (m) (2). [See *United States* v. *Dotterweich*, 320 U. S. 277, 280 (1943).] So it is my opinion that the scope of 'accompanying' should be limited under *Kordel* v. *United States*, *supra*, 335 U. S. 345 and *United States* v. *Urbuteit*, *supra*, 335 U. S. 355, to cases where the literature has the same destination as the drug and hence will likely reach the hands of the consumer to serve the purposes for which labeling is intended. [Cf. *Alberty* v. *United States*, 159 F. 2d 278 (9th Cir. 1947); also *Alberty Food Products* v. *United States*, *supra*, 185 F. 2d at 325.]

"It follows that in the case at bar the literature must be held as not 'accompanying' the drugs in interstate commerce and therefore as not constituting a part of the 'labeling.' [21 U. S. C. § 321 (m) (2).] The 'labels' alone then on each of the drugs in question [21 U. S. C. § 321 (k)] must be held to comprise the entire 'labeling' as to such drug.

"There remains the question whether the 'labeling' bears 'adequate directions for use' within the meaning of § 502 (f) (1) of the Act [21 U. S. C. § 352 (f) (1)].

"Labeling fails to bear 'adequate directions for use,' if it does not state 'the purpose or condition for which the drug was intended,' as well as the dosage

and frequency or duration of taking prescribed, recommended or suggested in connection with the diseases or conditions of the body for which such drug is held out to the public. [See 21 U. S. C. §§ 321 (n), 352 (f), 352 (j), 371 (a); 21 Code Fed. Regs. §1.106 (1949); *Colegrove* v. *United States*, 176 F. 2d 614, 616 (9th Cir. 1949); *United States* v. *Various Quantities* * * * *'Instant Alberty Food.'* 83 F. Supp. 882, 885 (S. D. Cal. 1949).]

"As Judge Bone said in *Alberty Food Products* v. *United States, supra*, 185 F. 2d at 325:

> We proceed upon the assumption that the "adequate directions for use" mandate of Sec. 352 (f) (1) requires that *all* who might want to use a drug * * * are at least entitled to a chance to somewhere find and examine a "label" which is complete enough to * * * provide sufficient information at the time of purchase upon which intelligent determination might be made as to whether the drug is one which is prescribed, recommended, or suggested for their particular * * * ailment. We are persuaded that the law requires this much.

"The following is typical of the 'labeling' of a majority of the drugs in the case at bar:

ALBERTY'S
SABINOL
Homeopathic
App. 525 Pellets
Each Pellet Contains
Berberis Vulgaris
Lycopodium
Manufactured for and Packed by
ALBERTY FOOD PRODUCTS
Hollywood, California
Directions:
Take 3 Pellets every 2 hours until
relieved. Then 4 times daily.

"Similar labels appear on defendants' products identified as:

Alberty's Vegetable Compound Capsules [Exhibit 1];
Alberty's Oxorin [Exhibit 2];
Alberty's Food Regular [Exhibit 3];
Instant Alberty Food [Exhibit 4];
Alberty Garlic Perles (Alberty Garlic and Vegetable Oil Perles) [Exhibit 5];
Alberty's Sabinol [Exhibit 6];
Alberty Phloxo B Tablets [Exhibit 7];
Alberty's Phosphate Pellets [Exhibit 8];
Alberty's Ri-Co Tablets [Exhibit 10];
Alberty Special Formula Tablets [Exhibit 11];
Wheat Germ Oil [Exhibit 14];
Alberty's Lebara Pellets, Plain [Exhibit 17];
Alberty's Lebara No. 2 Pellets [Exhibit 18];
Cheno Phytolacca Berry Juice Extract Tablets and Cheno Phytolacca Berry Juice [Exhibit 20];
Cheno Combination Tablets [Exhibit 21];
Pandora Tablets [Exhibit 22];
Recal Tablets [Exhibit 23]; and
Alberty's Ca-Mo Pellets [Exhibit 27].

"Such 'labeling' fails to state either 'the purpose or condition for which the drug was intended' or the duration of taking recommended for treatment of the diseases or conditions of the body for which the drug is held out to the public in defendants' literature.

"The remaining 'drugs' involved at bar, to wit:

Alberty Riol Tablets [Exhibit 9];
Alberty's Vitamin A (High Potency) Shark Liver Oil [Exhibit 12];
Alberty's Vi-C [Exhibit 13];
Alberty Vitamin B Complex Tablets with High-Potency B_1 [Exhibit 15];
Alberty's Vitamin B_1 Tablets with Supplementary Amounts of Other B-Complex Factors [Exhibit 16];
Cheno Herb Tea [Exhibit 19];
Alberty's Vio-Min Vitamin-Mineral Tablets [Exhibit 24];
Alberty R-Gon Tablets [Exhibit 25];
Alberty's Laxative Blend Tea [Exhibit 26];
Alberty's Vitamin A & G Capsules [Exhibit 28]; and
Alberty Rego [Exhibit 29].

may be classed as so-called dietary supplements and laxatives. As such 'the purpose or condition for which the drug was intended' is a matter of common knowledge.

"However defendants in their literature admittedly recommend these 'drugs' without exception for other than commonly known uses. For example, defendants recommend their Vitamin B_1 Tablets [Exhibit 16] in the pamphlet 'Calcium—The Staff of Life' [Exhibit 30] for 'preventing chronic ill health'; for 'certain cases of heart disease' and 'some cases of arthritis and neuritis'; for increasing 'the body's insulin output and sugar tolerance'; and for 'improving the intelligence of school children.'

"Yet the only directions for use appearing on the 'labeling' of Alberty's Vitamin B_1 Tablets are: *'Directions*—Two tablets, three times daily (six tablets a day) furnish 3½ times the minimum daily requirements of Vitamin B_1 for an adult, and $\frac{1}{10}$ such requirements of Vitamin B_2.'

"Comment on the manifest inadequacy of such labeling to give 'adequate directions for use' for the purpose recommended in defendants' literature would be surplusage indeed.

"The facts as to the 'labeling' of each 'drug' at bar being admitted, the Government is entitled to summary judgment for a writ of injunction permanently enjoining and restraining defendants from 'the introduction or delivery for introduction into interstate commerce' [21 U. S. C. § 331 (a)] of any of the 'drugs' involved in this action unless and until the labeling of each such 'drug' bears adequate directions for the use thereof in the treatment of the diseases and conditions of the body for which defendants in their literature and other advertising prescribe, recommend or suggest its use [*Colegrove* v. *United States, supra.* 176 F. 2d 614; *id.* 83 F. Supp. 880 (S. D. Cal. 1947)].

"Accordingly the Government's motion for summary judgment is granted, and the United States Attorney will submit proposed findings of fact, conclusions of law and judgment pursuant to local rule 7 within ten days."

In accordance with the foregoing opinion, the court handed down its findings of fact and conclusions of law on June 30, 1951. On the same day, the court entered an order permanently enjoining the defendant from introducing or delivering for introduction into interstate commerce, and from causing the introduction or delivery for introduction into interstate commerce, any of the above-named drugs or any other drug misbranded under Section 502 (f) (1), by reason of the failure of its labeling (1) to enumerate the disease conditions for which the drug was intended and offered to the public, (2) to specify the structures or functions of the body which it was intended to affect and for which it was offered to the public, and (3) to state the dosage, frequency, and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.

On July 24, 1951, the defendants filed a notice of appeal to the United States Court of Appeals for the Ninth Circuit. On February 15, 1952, after consideration of the briefs and arguments of counsel, the following opinion was handed down by that court, affirming the judgment of the district court:

ORR, *Circuit Judge:* "The facts of this case have been stipulated. They appear in detail in the opinion of the District Court (98 F. Supp. 23, D. C. S. D. Cal. 1951). For our purposes it is sufficient to state that appellants manufacture, pack and distribute certain drugs in interstate commerce. The District Court found the drugs in question to be 'misbranded' within the meaning of the Federal Food, Drug and Cosmetic Act in that their labeling failed to bear

'adequate directions for use.' 21 U. S. C. A. § 352 (f) (1). An injunction was issued permanently restraining appellants from introducing into interstate commerce said drugs or any other drug '* * * which is misbranded within the meaning of 21 U. S. C. § 352 (f) (1) by reason of the failure of its labeling (1) to enumerate the disease conditions for which said drug is intended and offered to the public, (2) to specify the structures or functions of the body which it is intended to affect and for which it is offered to the public, and (3) to state the dosage and frequency and duration of administration of such drug for the treatment or prevention of such conditions, or for affecting such structures or functions of the body.'

"The principal contention made on this appeal is that the trial court erred in taking into consideration, in making its finding that the drugs in question were misbranded, certain collateral literature (leaflets and booklets, etc.,)[1] sent by appellant to prospective customers. Appellants obtained customer names in various ways: (a) from retail outlets selling the drugs; (b) from demonstrators hired by appellants to work in retail outlets, and, (c) from customer inquiries and mail orders. Newspaper and magazine advertising was also used to promote sales of the drugs. These promotional materials contained claims, representations and suggestions relating to use of the drugs not present on the labels.[2] It is asserted by appellants that a consideration by the trial court of the literature and advertisements is an invasion of a field exclusively under the jurisdiction of the Federal Trade Commission, which has control of false advertising. This contention fails to grasp the scope and purpose of the inquiry with which the Court was concerned. It is not the truth or falsity of the literature and advertising which is challenged; it is merely consideration, as evidence, of claims promulgated by the manufacturer in measuring whether the information communicated by means of the label adequately describes the diseases or conditions for which the drug was intended as well as relevant facts containing dosage.

"In order for the labeling of a drug to bear 'adequate directions for use' within the meaning of 21 U. S. C. A. § 352 (f) (1) it must, among other things, state the purposes and conditions for which the drug was intended and sufficient information to enable a layman to intelligently and safely attempt self medication. Alberty Food Products v. United States, 185 F. 2d 321, 325 (9 Cir. 1950); Cf. H. Rep. No. 2139, 75th Cong., 3d Session 8.

"While appellants agree with this construction they argue that such fact must be determined from the labeling alone. This contention is without merit. It is not sufficient that the labeling contain a minimum of information and the use of the drug be induced by elaborate collateral representations. To permit the operation of such an escape valve would render the aims and purposes of labeling requirements nugatory. Adequate labeling is best suited to obtain the beneficent purposes contemplated by the Act, viz: broad protection of the consumer from adulterated or misbranded drugs, etc., and as a practical matter places no burden on those motivated by an honest belief that the claims made for their drug will be accomplished by its use.

"In the instant case appellants argue that the drugs involved in this case can properly be classified as 'dietary supplements and laxatives,' and labeling to that effect is sufficient, because such uses and purposes are of common knowledge. Such an argument has no validity because it is admitted that the drugs have been held out to the public as having beneficial and curative qualities other than their commonly known uses.

"The finding of the trial Court that the labels in question do not bear adequate directions for use finds ample support in the law and evidence. See United States v. Various Quantities of Articles of Drugs, 83 F. Supp. 882 (D. C. D. C. 1949); Colegrove v. United States, 176 F. 2d 614 (9 Cir. 1949),

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[1] The leaflets and booklets were entitled, "Calcium, The Staff of Life," "Dynamic Digests," "Is There Hope That Graying Hair Can Be Restored? Read What Science Says—Pandora," "Health Mysteries," "Happy Figures by the Cheno Plan," "Reduce! Streamline Your Figure—Follow the 5 Factor Cheno Plan."

[2] For example, one of the drugs involved is Alberty's Garlic & Vegetable Oil Perles. The label simply states, "Fresh Garlic Concentrated Eight to One and Combined in Vegetable Oil," "One or 2 Perles Before Meals, a Convenient Way of Including Garlic in the Diet." In the collateral literature "Perles" are mentioned in connection with high blood pressure, various gastro-intestinal disorders, heart failure, hardening of the arteries, gastritis, some forms of dyspepsia, peptic ulcer, exerting an anti-diarrheal effect in gastro-intestinal disease, etc.

Cert. den. 338 U. S. 911 (1950); Alberty Food Products v. United States, 185 F. 2d 321 (9 Cir. 1950); United States v. El-O-Pathic Pharmacy, 192 F. 2d 62, 77 (9 Cir. 1951).

"Judgment affirmed."

3664. Alleged misbranding of Kordel-E capsules, Aminex tablets, Fero-B-Plex tablets, and Garlic Plus tablets. U. S. v. 1 Case, etc. (F. D. C. No. 27269. Sample Nos. 57736–K, 57737–K, 57741–K, 57743–K.)

LIBEL FILED: May 26, 1949, Southern District of California; amended libel filed June 2, 1949.

ALLEGED SHIPMENT: On or about July 30, 1948, to April 7, 1949, from Chicago, Ill.

PRODUCT: 1 case of 36 30-capsule boxes of *Kordel–E capsules*, 1 case of 20 100-tablet boxes of *Aminex tablets*, 1 case of 29 90-tablet boxes of *Fero-B-Plex tablets*, and 96 50-tablet boxes of *Garlic Plus tablets* at Los Angeles, Calif.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since it did not state the diseases or conditions of the body for which the articles when used as directed would be effective. The products were alleged to be misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: Lelord Kordel appeared as claimant and filed an answer to the libel. Thereafter, on February 29, 1952, upon stipulation by the parties that the case presented no question for adjudication for the reason that the products under seizure had deteriorated and become unmarketable, and without any finding by the court on any issue of fact or law and with the consent of the parties, judgment was entered ordering that the products be destroyed.

3665. Misbranding of amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Enos A. Hilterbrand (Live Oak Pharmacy). Plea of guilty. Sentence of 2 years in prison. (F. D. C. No. 31258. Sample Nos. 20962–L, 20963–L.)

INFORMATION FILED: September 17, 1951, Northern District of Texas, against Enos A. Hilterbrand, trading as Live Oak Pharmacy, Dallas, Tex.

INTERSTATE SHIPMENT: From the States of New Jersey and Indiana into the State of Texas, of quantities of *amphetamine sulfate tablets* and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about May 30, 1951, while the drugs were being held for sale at the Live Oak Pharmacy after shipment in interestate commerce, various quantities of the drugs were repacked and sold without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *amphetamine sulfate tablets* and the *Seconal Sodium capsules* failed to bear labels contain-

ing the common or usual name of the drugs; and, Section 502 (f) (1), the repackaged *amphetamine sulfate tablets* and the *Seconal Sodium capsules* failed to bear labeling containing adequate directions for use.

DISPOSITION: November 29, 1951. A plea of guilty having been entered, the court sentenced the defendant to 2 years in prison.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3666. Adulteration of peppermint leaves, spearmint leaves, and lobelia leaves. U. S. v. Arthur P. Slaughter (Smoky Mountain Drug Co.). Plea of nolo contendere. Fine, $250. (F. D. C. No. 31087. Sample Nos. 24131–L, 24132–L, 24134–L.)

INFORMATION FILED: June 1, 1951, Eastern District of Tennessee, against Arthur P. Slaughter, trading as the Smoky Mountain Drug Co., Bristol, Tenn.

ALLEGED SHIPMENT: On or about October 18 and November 20, 1950, from the State of Tennessee into the State of New Jersey.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the products consisted in part of filthy substances by reason of the presence of rodent excreta, rodent hairs, and insect fragments, in the *peppermint leaves*; rodent excreta, in the *spearmint leaves*; and insects and rodent excreta, in the *lobelia leaves*.

Further adulteration, Section 501 (a) (2), the products had been prepared and packed under insanitary conditions whereby they may have become contaminated with filth.

The information charged also the interstate shipment of an adulterated food, as reported in notices of judgment on foods.

DISPOSITION: September 17, 1951. A plea of nolo contendere having been entered, the court fined the defendant $250 on the counts based on the shipment of adulterated drugs. (A fine of $250 was imposed also on the counts charging the other violations.)

3667. Adulteration of chamomile flowers. U. S. v. 10,936 Pounds * * *. (F. D. C. No. 32020. Sample No. 4859–L.)

LIBEL FILED: November 13, 1951, District of Massachusetts.

ALLEGED SHIPMENT: On or about February 23, 1951, from Jersey City, N. J.

PRODUCT: 10,936 pounds (14 bales) of *chamomile flowers* at Lynn, Mass.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 26, 1951. The Lydia E. Pinkham Medicine Co., Lynn, Mass., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reconditioning, under the supervision of the Federal Security Agency. Reconditioning consisted of fumigation with methyl bromide, sifting, and blowing.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3668. Adulteration and misbranding of sodium chloride solution, procaine hydrochloride solution, and Darrow's solution. U. S. v. Continental Pharma-

cal Co. and Lawrence W. Jordan. Pleas of nolo contendere. Corporation fined $1,000; individual defendant fined $250. (F. D. C. No. 30604. Sample Nos. 14748-K, 47674-K, 54856-K, 66834-K, 74522-K.)

INFORMATION FILED: On or about July 19, 1951, Northern District of Ohio, against the Continental Pharmacal Co., a corporation, Cleveland, Ohio, and Lawrence W. Jordan, president of the corporation.

ALLEGED SHIPMENT: On or about February 4, 1949, and February 1, April 13, and May 25, 1950, from the State of Ohio into the States of Michigan, North Carolina, Texas, and New York.

LABEL, IN PART: (Bottle) "1000 cc. [or "500 cc.] Sodium Chloride 3% In Distilled Water Each 100 cc. Contains: W/V Sodium Chloride U. S. P. 3.0 Gm. * * * This product is sterile and non-pyrogenic. * * * The Continental Pharmacal Co. Cleveland, Ohio," "Procaine Hydrochloride 0.1% * * * Each 100 cc contains: Procaine HCl 0.1 gm * * * Sterile Non-Pyrogenic," and "Darrow's Solution Each 100 cc. Contains W/V Sodium Chloride 0.4 Gm. Potassium Chloride 0.26 Gm. Sodium Lactate 5.33 cc. of a Molar solution * * * This product is sterile and non-pyrogenic."

NATURE OF CHARGE: *Sodium chloride solution.* Adulteration, Section 501 (b), the article purported to be "Isotonic Sodium Chloride Solution," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the standard set forth in that compendium; and its difference in strength from the official standard was not plainly stated on its label. Misbranding, Section 502 (a), the label statements "Sodium Chloride 3% In Distilled Water Each 100 cc. Contains: W/V Sodium Chloride U. S. P. 3.0 Gm." were false and misleading since the article contained less than 3 percent of sodium chloride, and 100 cc. contained less than 3 grams of sodium chloride.

Procaine hydrochloride solution. Adulteration (1 shipment), Section 501 (c), the strength of the article differed from that which it was represented to possess in that it was represented to contain 0.1 percent of procaine hydrochloride and each 100 cc. was represented to contain 0.1 gram of procaine hydrochloride, whereas it contained less than 0.1 percent of procaine hydrochloride and each 100 cc. of the article contained less than 0.1 gram of procaine hydrochloride. Misbranding (1 shipment), Section 502 (a) the label statements "Procaine Hydrochloride 0.1% * * * Each 100 cc. contains: Procaine HCl 0.1 gm" were false and misleading since the article contained less than 0.1 percent of procaine hydrochloride and each 100 cc. contained less than 0.1 gram of procaine hydrochloride. Adulteration (remaining shipment), Section 501 (c), the purity and quality of the article fell below that which it was represented to possess since it was represented to be sterile, whereas it was not sterile but was contaminated with viable micro-organisms. Misbranding (remaining shipment), Section 502 (a), the label statement "Sterile" was false and misleading since the article was not sterile.

Darrow's solution. Adulteration Section 501 (c), the strength of the article differed from that which it was represented to possess since each 100 cc. was represented to contain 5.33 cc. of a molar solution of sodium lactate, whereas each 100 cc. of the article contained less than 5.33 cc. of a molar solution of sodium lactate. Misbranding Section 502 (a) the label statement "Each 100 cc. Contains: * * * Sodium Lactate 5.33 cc. of a Molar solution" was false and misleading since each 100 cc. of the article contained less than 5.33 cc. of a molar solution of sodium lactate.

DISPOSITION: January 4, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $1,000 against the corporation and a fine of $250 against the individual defendant.

3669. Adulteration and misbranding of Liver – Iron – Vitamins (injection). U. S. v. Taylor Pharmacal Co. Plea of nolo contendere. Fine, $100. (F. D. C. No. 31280. Sample No. 24678–L.)

INFORMATION FILED: December 27, 1951, Southern District of Illinois, against the Taylor Pharmacal Co., a corporation, Decatur, Ill.

ALLEGED SHIPMENT: On or about March 2, 1951, from the State of Illinois into the State of New York.

LABEL, IN PART: (Vial) "Multiple Dose Vial 10 CC. Size Liver – Iron – Vitamins * * * Syracuse Pharmacal Co., Inc. Syracuse, N. Y., Distributors."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each 2 cc. contains: * * * Riboflavin ____ 0.3 mg."

Misbranding, Section 502(a), the label statement "Each 2 cc. contains: * * * Riboflavin ____ 0.3 mg." was false and misleading since each 2 cc. of the article contained less than 0.3 milligram of riboflavin.

DISPOSITION: January 24, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $100.

3670. Adulteration and misbranding of liver extract (injection). U. S. v. 12 Boxes * * *. (F. D. C. No. 32155. Sample No. 38570–L.)

LIBEL FILED: November 16, 1951, District of New Jersey.

ALLEGED SHIPMENT: On or about October 9, 1951, by the Lederle Laboratories, from Pearl River, N. Y.

PRODUCT: 12 boxes, each containing 3 1-cc. vials, of *liver extract* at Newark, N. J.

LABEL, IN PART: (Box) "Lederle Concentrated Solution Liver Extract 15 U (Liver Injection U. S. P.) * * * Each cc * * * constitutes 15 U. S. P. units injectable * * * each cc contains 20 Microgm of Vitamin B_{12} by biological assay."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "each cc contains 20 Microgm of Vitamin B_{12} by biological assay" was false and misleading since the article contained less than 2 micrograms of vitamin B_{12} per cubic centimeter.

DISPOSITION: January 29, 1952. Default decree of condemnation. The court ordered that samples be delivered to the Food and Drug Administration and that the remainder be destroyed by the United States marshal.

3671. Adulteration and misbranding of Vidodec. U. S. v. 370 Vials * * *. (F. D. C. No. 32137. Sample No. 21134–L.)

LIBEL FILED: November 27, 1951, Western District of Texas.

ALLEGED SHIPMENT: On or about July 1, 1951, from New York, N. Y.

PRODUCT: 370 10-cc. vials of *Vidodec* at San Antonio, Tex.

LABEL, IN PART: "Injectable Vidodec 10 cc. Sterile Solution Each cc. contains Vitamin B_1 25 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Each cc contains Vitamin B_1 25 mg." was false and misleading since the article contained less than 25 mg. of vitamin B_1 per cubic centimeter. (Examination disclosed that the article contained approximately 16.7 mg. of vitamin B_1 per cubic centimeter.)

The product was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 4, 1952. Default decree of forfeiture and destruction.

3672. Adulteration and misbranding of Estrotron (estrogenic hormone). U. S. v. 52 Bottles, etc. (F. D. C. No. 31206. Sample No. 23573–L.)

LIBEL FILED: June 21, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about April 17 and 24, 1951, by the Pitman-Moore Co., from Indianapolis, Ind.

PRODUCT: 52 10-cc. size bottles of *Estrotron* at New York, N. Y., together with leaflets entitled "Estrotron." Examination of the article showed that some of the bottles contained not more than 1.42 milligrams of estrogenic ketosteroids per cubic centimeter.

LABEL, IN PART: (Bottle and carton) "10 cc Size * * * Estrotron, 2 mg. (20,000 I. U.) per cc. in Peanut Oil A highly purified estrus producing extract from the urine of pregnant mares."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 2 milligrams of estrogenic ketosteroids per cubic centimeter.

Misbranding, Section 502 (a), the label statements (bottle and carton) "Estrotron, 2 mg. (20,000 I. U.) per cc * * * consisting primarily of estrone with smaller amounts of naturally occurring estrogens * * * standardized to 20,000 I. U. of activity per cc" and (leaflet entitled "Estrotron") "containing 2 mg. of estrogenic substance per cc. equal in estrogenic activity to 20,000 I. U. per cc." were false and misleading as applied to an article which contained less than the declared amount of estrogenic ketosteroids per cubic centimeter.

DISPOSITION: November 29, 1951. The Pitman-Moore Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the article be released under bond for treating or reprocessing so that the article would contain the declared amount of estrogenic ketosteroids per cubic centimeter, under the supervision of the Federal Security Agency.

3673. Adulteration of yerba santa and grindelia. U. S. v. 4 Sacks, etc. (F. D. C. No. 30880. Sample Nos. 27834–L to 27836–L, incl.)

LIBEL FILED: April 2, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about March 2, 1951, by J. G. Olvey, from Colusa, Calif.

PRODUCT: 4 100-pound sacks of *yerba santa* and 22 200-pound bales of *grindelia* at New York, N. Y.

NATURE OF CHARGE: *Yerba santa.* Adulteration, Section 501 (b), the product purported to be and was represented as "Yerba Santa," a drug, the name of which is recognized in the National Formulary, an official compendium, and

its quality fell below the standard set forth in the compendium since it contained more than 5 percent of its stems.

Grindelia. Adulteration, Section 501 (b), the product purported to be and was represented as "Grindelia," a drug, the name of which is recognized in the National Formulary, an official compendium, and its quality fell below the standard set forth in the compendium since it contained more than 10 percent of its stems over 2 mm. in diameter.

DISPOSITION: June 21, 1951. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond to be brought into compliance with the law by segregation and destruction of the portion of the *yerba santa* which could not be successfully salvaged; the treatment of the remainder of the *yerba santa* by fumigating, cutting, or sifting, so as to eliminate and destroy the objectionable substances; and the relabeling of the *grindelia* in order that each bale show its variation from the National Formulary. 609 pounds of the *yerba santa* were salvaged and 88 pounds were destroyed.

3674. Adulteration of Gauztex. U. S. v. 9 Dozen Packages * * *. (F. D. C. No. 31484. Sample No. 27949–L.)

LIBEL FILED: August 22, 1951, Northern District of California.

ALLEGED SHIPMENT: On or about September 18, 1946, from Chicago, Ill.

PRODUCT: 9 dozen packages of *Gauztex* at Modesto, Calif.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug, the name of which is recognized in the United States Pharmacopeia, and its quality and purity fell below the standard set forth in the United States Pharmacopeia since it was not sterile as required by the Pharmacopeia but was contaminated with viable micro-organisms. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 31, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3675. Misbranding of various drugs. U. S. v. 4 Packages, etc. (F. D. C. No. 31143. Sample Nos. 18052–L to 18058–L, incl., 18062–L to 18070–L, incl., 18072–L, 18073–L, 18075–L to 18080–L, incl., 18082–L to 18087–L, incl., 18090–L, 18091–L, 18094–L to 18099–L, incl., 18101–L to 18113–L, incl., 18115–L to 18118–L, incl., 18121–L, 18123–L to 18128–L, incl., 18130–L.)

LIBEL FILED: May 22, 1951, District of Arizona.

ALLEGED SHIPMENT: Between March 15 and November 8, 1950, by Seroyal Brands, Inc., from Orinda, Calif.

PRODUCTS: Various drugs labeled, in part, as described below, at Tucson, Ariz., together with a folder entitled "Seroyal Brands," a number of leaflets, each containing 2 inserts, entitled "Why Orinda Lucerne?" a number of leaflets entitled "Seroyal Brands * * * Orinda Lucerne," and a number of leaflets entitled "Seroyal-Bulletin."

*See also Nos. 3662, 3663, 3668–3672.

LABEL, IN PART: "Ipomoea Tea 2 Ounces," "No. 30 45 Capsules * * * 30 Mg. Vitamin 'E'," "No. 57 45 Tablets * * * Duodenum Substance," "45 Tablets * * * Vitamin 'A' Tablets * * * Two Tablets contain 10,000 U. S. P. Units of Vitamin A," "45 Tablets * * * Vitamin B Complex Tablets * * * Ingredients: Yeast Concentrate, Malt Diastase, Calcium Carbonate," "No. 12 Orinda-Lucerne An extractive of lucerne 8 Ounce Liquid," "No. 41 Contents ½ Fluid Ounce A glycerine solution of extractives from Dulse and Alfalfa," "No. 5 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Cabbage, Potato Peel, Onion, Psyllium and Arrow Root," "No. 6 45 Tablets * * * Vegetable Tablets * * * Ingredients: Green Peas, Beet Root, Parsnip, Carrot Leaf, Cranberry," "No. 7 45 Tablets * * * Vegetable Tablets * * * Ingredients: Carrot, Endive, Tomato, Onion, Okra, Celery Stalk, Horseradish," "No. 8 2 Oz. Liquid * * * Soyapro * * * A Protein Hydrolysate prepared from Soya Flour Casein and Lactalbumin," "No. 9 One Fluid Ounce * * * Chloro-Green * * * Purified water-soluble derivatives of chlorophyll 'a' extracted from clover alfalfa and other grasses * * * with 15% propylene glycol," "No. 10 45 Tablets * * * Each Tablet Contains: Vitamin C 90 mgs., Chlorophyll 5 mgs., Spiraea Ulmaria 10 grs.," "No. 11 45 Wafers * * * Orinda-Lucerne Ingredients: Powdered Alfalfa Juice. Dextrose and excipients," "No. 13 45 Tablets * * * Turnip Leaves Juice Concentrate Tablets Each tablet contains: Sulphur from organic material (turnip) 100 Mgs.," "No. 14 2-Oz. * * * Spiraea Ulmaria Tea," "Juglins Nigra Tea One Ounce," "Equisetum Hiemale Tea 2 Ozs. net weight," "No. 21 25 Tablets * * * Each tablet contains: Vitamin C (Ascorbic Acid) 100 Mgs. Vitamin E (Mixed Tocopherols) 5 Mgs., Rutin 20 Mgs., Dextrin Maltose as excipients," "No. 22 45 Tablets * * * Vegetable Tablets * * * Ingredients: Beet Leaves, Kelp, Horseradish, Chicory, Pumpkin Seed," "No. 23 45 Tablets * * * Vegetable Tablets * * * Ingredients: Okra, Rhubarb Stalk, Red Cabbage, Hubbard Squash, Dulse, Beet Leaves, Cayenne," "No. 24 45 Tablets * * * Vegetable Tablets * * * Ingredients: Mint, Cranberry, Rhubarb Stalk, Dulse, Cloves, Dextrose," "No. 25 45 Tablets * * * Live Yeast Compound 8 grs. Papain 2 Grs. Ingredients: Acidophilus, Yeast, Barley, Hops, Malt Syrup, Dextrose and Levulose, Rye, Corn, Tapioca and Rice Flours, Papain," "#26 45 Tablets * * * Vegetable Tablets * * * Ingredients: Raphanus Nigra gr. 6½, Parsley q. s., Sugar coated, vegetable binder," "No. 28 45 Perles * * * Vitamin A–D Two capsules contain: Vitamin A 10,000 U. S. P. Units, Vitamin D 1,000 U. S. P. Units, Vitamins contained in refined fish liver oils," "No. 29 45 Perles * * * 5 Mg. Vitamin 'E' (Alpha Tocopherol) Wheat Germ Oil fortified with natural mixed tocopherols distilled from vegetable oils," "No. 31 45 Tablets * * * Vitamin 'C' Dietary Supplement * * * Ingredients: Dried Powdered uncooked Lemon Juice, Whole Orange, Gum Binder, Special Sugar Coating, colored with certified food coloring. Vitamin C as from Ascorbic Acid." "No. 32 45 Tablets * * * Six Tablets Contain: Vitamin A 5,000 U. S. P. Units, Vitamin C 30 Mgs., Vitamin B_1 1 Mg., Vitamin D 400 U. S. P. Units, Vitamin B_2 2 Mgs., Chlorophyll 10 Mgs., Together with Live Yeast, Dried, Powdered, uncooked Turnip Leaves, Lettuce, Spinach, Beet Leaves, Watercress and Alfalfa," "No. 33 45 Tablets * * * 100% Papain," "No. 34 45 Tablets * * * Chlorophyll-Papain Tablets * * * Ingredients: Chlorophyll, Papain, with dried, powdered, uncooked Lettuce, Parsley, Watercress, Kelp, Orange and Iron Sulfate. Copper (a trace), Di-

Calcium Phosphate," "No. 36–F 45 Tablets * * * Derived from essential unsaturated, fatty acids; arachidonic, linolenic, lineolic from flax and beef lipoids. Each tablet contains .5 mgs. of organically combined iodine," "No. 37 45 Tablets * * * Each Tablet contains: Calcium Carbonate (Derived from Egg Shells) 200 Mgs., Vitamin D (Irradiated Yeast) 200 U. S. P., Papain 1 Gr., Citric Acid 1 Gr., and Excipients," "No. 42 * * * Active Ingredients: Ortho-Phosphoric Acid, Calcium Phytate from Cereal Sources, Carrier Material, Corn Starch and Gum Arabic * * * Contents 1½ Ounces," "No. 43 45 Tablets * * * Yeast-Calcium Each tablet contains: Live Yeast 7 Grs., Egg Calcium, 3 grs., Glucose, 2 grs., and excipients," "No. 44 45 Tablets * * * 12 tablets contain: Vitamin B_1 (Thiamin) 1 mg., Vitamin B_2 (Riboflavin) 3 mgs. In a base of powdered Spineless Cactus (Opuntia Fraflis)," "No. 46 45 Tablets * * * Three tablets contain: Vitamin B_1 (Thiamin Hcl) 3 Mgs.," "No. 47 45 Tablets * * * Each tablet contains: Vitamin A (Fish liver oil) 500 U. S. P. Units, Vitamin B–1 (Thiamin Hcl) ½ Mg., Vitamin B–2 (Riboflavin) ½ Mg., Niacin Amide 1 Mg., Vitamin C (Ascorbic Acid) 10 Mg., Maltose and Dextrin as Excipients and Hydrolized Natural Plant Proteins," "No. 48 45 Tablets * * * Three tablets contain: Vitamin B_1 (Thiamin Hcl) 1 Mg., Vitamin C (Ascorbic Acid) 10 Mgs., Iron (Iron Tartrate) 15 Mgs., Together with Liver Conc., Stomach Sub., Hemoglobin Red Bone Marrow, Kelp & Brewers Yeast," "No. 50 45 Perles * * * Extract of Garlic In Vegetable Oils Each perle contains: Odorless true extract of garlic in the same proportion as found in the whole garden fresh garlic pulp, suspended in cold pressed wheat germ, soybean, olive and dill oils," "No. 51 45 Perles * * * Vitamin A–E * * * Ingredients in each Capsule: Vitamin A (fish liver oil) 5,000 U. S. P. Units, Chlorophyll (Sodium Magnesium Chlorophyllin) .5 Mg., Odorless Garlic .5 Mg., Wheat Germ Oil 171 Mgs. Plus natural flavors," "No. 53 45 Tablets * * * Russian Radish, Parsley, Sugar Beet Extract, Choline, Hydrochloride, Methionine," "No. 54 45 Tablets * * * Desiccated Cactus (Optunis Faralis), Betain (from Sugar Beets), Chlorophyll (from Alfalfa)," "No. 56 45 Tablets * * * Primary Yeasts, Skimmed Milk and Soya Meal," "B–81 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Beet leaves, Parsley, Celery leaves, Watercress, Escarole, Rhubarb Stalk and Turnip leaves," "No. K–82 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Asparagus, Lettuce, Spinach, Beet leaves and Kale," "D–83 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Cauliflower, Celery leaves, Lettuce, Spinach, Tomato, Turnip leaves, Asparagus and Watercress," "No. A–84 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Spinach, Lettuce, Turnip leaves, Watercress, Beet leaves and Endive," "S–85 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Red Cabbage, Carrot leaves, Onion, Garlic and Horseradish," "No. G–86 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Beet leaves, Endive, Celery leaves, Watercress and Spinach," "R–87 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Escarole, Lettuce, Spinach, Celery leaves, Turnip leaves, Watercress, Carrot leaves and Horseradish," "No. N–88 45 Tablets * * * Vegetable tablets * * * Ingredients: Dried, powdered, uncooked Lettuce, Pumpkin, Endive, Carrot leaves and Dulse," "V–90 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Rice

polish, Rice bran, Green Celery, Cauliflower and mint," "No. 91 45 Tablets * * * ingredients: Clivers, Buchu, juniper berries, couch grass, uva, ursi, gravel root, stone root, cubebs, agrimony, dandelion, golden rod and asparagus," "U–92 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Okra, Japanese persimmon, Orange and Celery Stalk," "No. H–93 45 Tablets * * * Vegetable Tablets * * * Ingredients: Dried, powdered, uncooked Parsley, Lettuce, Kale, Garlic and Dulse," "No. W–96 45 Tablets * * * Ingredients: The active laxative is dried, powdered Rhubarb root in a very small quantity. In addition each tablet contains dried, powdered, uncooked Irish moss, Celery leaves, Spinach, Dulse, Rhubarb Stalk, Parsley and Okra. Cinnamon used as a flavor," "No. 98 6 Tablets * * * Chlorophyll Contents to make 3 Oz. of 3 mgs. water-soluble Chlorophyll per cc," "No. F–99 45 Tablets * * * Vegetable & Vitamin Tablets Ingredients: Dried, powdered, uncooked Watercress, Turnip leaves, Mustard greens, and Beet leaves with Vitamins A B C D G added," "Y–100 45 Tablets * * * Vitamin, Vegetable and Live Yeast Tablets Ingredients: Dried, powdered, uncooked Turnip leaves, Lettuce, Spinach, Beet leaves, Watercress and Alfalfa, with a larger portion of Live Yeast. Vitamins A, B, C, D and Riboflavin (G–B) added," "No. 101 45 Tablets * * * Live Yeast Tablets Ingredients: Acidophilus, Yeast, Barley, Hops, Malt Syrup, Dextrose and Levulose, Rye, Corn, Tapioca and Rice flours," "45 Tablets * * * Vitamin 'C' Tablets * * * Ingredients: Dried, powdered, uncooked lemon. Special sugar syrup. Vegetable gum binder. Vitamin C as from ascorbic acid," "45 Tablets * * * Vitamin 'D' Tablets With Calcium and Phosphorus * * * Ingredients: Dicalcium Phosphate, Vitamin D as from yeast concentrate activated by irradiation. Special Sugar Binder," and "45 Tablets * * * Vitamin 'G' Tablets With Vitamins B_1 and Niacin * * * Ingredients: Yeast concentrate. Grain derivative. Malt diastase. Special sugar syrup, Vegetable gum binder. Vitamin G–B_2 from natural grain sources. Vitamin B_1 from yeast. Nicotinic acid."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the accompanying folder entitled "Seroyal Brands" were false and misleading since the articles were not adequate and effective treatments for the conditions stated and implied, namely (*Ipomoea Tea*) "Internal growths. Fibroid Tumor"; (*No. 30*) "Heart, Muscles and pain in soft tissue"; (*No. 57*) "Stomach ulcers . . . . . intestinal irritations. Colitis * * * Gastric Ulcer"; (*vitamin "A" tablets*) "Staphylococci * * * Pneumococcus * * * B. Tuberculosis * * * Diphtheria * * * Cancer * * * Diphtheroids * * * Influenza"; (*vitamin "B" complex tablets*) "Cancer"; (*No. 11*) and (*No. 12*) "Sarcina * * * B. Coli * * * B. Typhoid * * * M. Meningitis * * * Trypanosome * * * Kidney Stone * * * Gall Stone * * * Polio vir. * * * Tularemia * * * Blood Sugar * * * Asthma * * * Rheumatic Fever * * * Sinusitis * * * Diphtheroids * * * Psoriasis * * * Erythrocytes * * * Leucocytes"; (*No. 41*) "Thyroid, nervousness * * * Streptococci * * * Diphtheria * * * B. Typhoid * * * Syphilis * * * Trypanosome * * * E. Histolytica * * * B. abortus (Undulant Fever) * * * Anthrax * * * Tularemia * * * Bronchitis * * * Asthma * * * Polyposis * * * Diphtheroids * * * Vincent's Angina * * * Relapsing Fever * * * Eczema squamosum (dry scaly) * * * Cirrhosis of Liver * * * Impetigo * * * Actinomycosis * * * Samonella pullorum (enteric disease of

chickens) * * * Mastitis"; (*No. 5*) "Over-acid conditions"; (*No. 6*) "Over-alkaline conditions"; (*No. 7*) "Over-weight conditions"; (*No. 8*) "Indicated in most all chronic conditions, particularly in older people"; (*No. 9*) "Catarrhalis * * * Sinusitis * * * Vincent's Angina * * * Influenza * * * Hay Fever (allergy)"; (*No. 10*) "Tetanus * * * Sarcina, Polio and other types of contracted muscles. M. meningitis"; (*No. 13*) "contraction of the bladder, causing frequent urination as well as crampy sensation in the pubic region of the body; the digestive function may become impaired and the patient may be 'puffy'; and in a woman the menses may be spasmodic with crampy pain during the menstrual function"; (*No. 14*) "Gives tone to the muscles. Use on Sarcina & Polio cases, or other evidence of contracting muscles"; (*Juglins Nigra Tea*) "Gonococci * * * Malaria"; (*Equisetum Hiemale Tea*) "Burning Bladder"; (*No. 21*) "High Blood Pressure; Fragile Capillaries"; (*No. 22*) "Vermifuge * * * Eradication of intestinal infestations, and many types of worms, Trichina * * * Worms * * * Filariasis * * * Samonella pullorum (enteric disease of chickens)"; (*No. 23*) "Metallic poisonings: Aluminum, Lead, etc."; (*No. 24*) "Copper poisoning"; (*No. 25*) "Digestive disturbances"; (*No. 26*) "Gall Bladder, Gall stones, Liver, Bursitis"; (*No. 28*) "Resistance to infections, such as colds Pneumococcus"; (*No. 29*) "Heart, Muscles, and pain in soft tissue"; (*No. 31*) "Resistance to colds, Alcoholuric jaundice * * * Familial jaundice"; (*No. 32*) "B. Abortus (Undulant Fever) * * * Anthrax * * * Tularemia * * * Nephritis * * * Relapsing Fever * * * Impetigo"; (*No. 33*) "Digestive B. Typhoid * * * E. Histolytic * * * Asthma"; (*No. 34*) "Blood infections, B. Abortus, Sarcina"; (*No. 36-F*) "Calcium metabolizer, prostate, hair, nails, skin, etc."; (*No. 37*) "B. Tuberculosis * * * Asthma * * * Psoriasis * * * Hay Fever (allergy)"; (*No. 42*) "Kidney Stone * * * Psoriasis * * * Hay Fever (allergy)"; (*No. 42*) "Kidney Stone * * * Psoriasis * * * Cirrhosis of Liver * * * Bursitis"; (*No. 43*) "Digestive disturbances, muscles, nerves, constipation. M. meningitis * * * Polio vir. * * * Asthma"; (*No. 44*) "Heart conditions . . . . . Pancreas. M. meningitis * * * Polio vir. * * * Blood sugar"; (*No. 46*) "Female Gland"; (*No. 47*) "Protein starved conditions. B. Tuberculosis"; (*No. 48*) "Red cell count * * * Banti's Disease * * * Erythrocytes * * * Familial Jaundice"; (*No. 50*) "High Blood Pressure * * * intestinal parasites. Trichina"; (*No. 51*) "Infections B. Abortus (Undulant fever) * * * Relapsing fever"; (*No. 53*) "Gall Bladder . . . . . Liver Better results on fatty Liver and Cirrhosis. Kidney-stone * * * Gall-stone * * * Banti's disease * * * Cirrhosis of Liver * * * Alcoholuric jaundice * * * Familial jaundice"; (*No. 54*) "Heart . . . Pancreas . . . Menopause. Blood sugar"; (*No. 56*) "Anemia . . . Low Red Cell Count . . . Protein starvation . . . Aminos . . . B. Tuberculosis * * * Erythrocytes * * * Alcoholuric jaundice"; (*No. B–81*) "Low & High white cell count . . . Sulfanilamide poisonings. Rheumatic fever * * * Nephritis * * * Infectious mononucleosis * * * Relapsing fever * * * Leucocytes * * * Actinomycosis * * * Streptococci * * * Staphylococci * * * M. catarrhalis * * * Sarcina * * * Gonococcus * * * Malaria * * * B. Abortus (Undulant Fever) * * * Anthrax * * * Tularemia"; (*No. K–82*) "Calcification. Bursitis"; (*No. D–83*) "Genito Urinary irregularities"; (*No. A–84*) "Acid Alkaline imbalance"; (*No. S–85*) "Respiratory disturbances . . . sinus. Bronchitis * * * Sinusitis * * * Polyposis * * * Asthma"; (*No. G–86*) "Digestive disturbances, Colitis

* * * Gastric Ulcer"; (*No. R–87*) "Low red cell count . . . Infectious mononucleosis * * * Erythrocytes"; (*No. N–88*) "Nerve food, Bursitis"; (*No. V–90*) "Tired feeling . . . Exhaustion"; (*No. 91*) "Kidney Diuretic Rheumatic fever * * * Nephritis"; (*No. U–92*) "Intestinal irritation. Stomach Ulcers. Colitis * * * Gastric Ulcer"; (*No. H–93*) "Putrefaction in digestive tract"; (*No. W–96*) "Over-Weight"; (*No. 98*) "Poison oak * * * M. Catarrhalis * * * B. Abortus (Undulant fever) * * * Sinusitis * * * Nephritis * * * Polyposis * * * Vincent's Angina * * * Relapsing fever * * * Filariasis * * * Tetanus * * * Eczema madidans (weeping) * * * Influenza * * * Actinomycosis * * * Samonella pullorum (enteric disease of chickens)," (*No. F–99*) "Run down conditions"; (*No. Y–100*) "Low Vitality . . . Loss of Vigor. Asthma"; (*No. 101*) "Forms lactic acid, preventing growth of undesirable micro-organisms in intestinal tract. B. Tuberculosis * * * B. Coli * * * Eczema squamosum (dry scaly) * * * Eczema madidans (weeping) * * * Impetigo"; (*Vitamin C Tablets*) "Pneumococcus * * * B. Tuberculosis * * * Diphtheria * * * Cancer * * * Influenza * * * Leucocytes"; (*Vitamin D Tablets*) "Cancer * * * Psoriasis"; and (*Vitamin G Tablets*) "B. Tuberculosis * * * Cancer * * * Colitis * * * Gastric Ulcer."

Further misbranding, Section 502 (a), certain statements in the labeling of the *No. 11* and the *No. 12*, namely, in the leaflets including the inserts entitled "Why Orinda Lucerne?" and in the leaflet entitled "Seroyal Brands * * * Orinda Lucerne," were false and misleading since the articles were not capable of producing the results claimed. The statements represented and suggested that the articles, because of their calcium content, would promote healing of wounds, prevent impaired digestion, acid stomach, belching, flatulence, loss of tone and resistance in heart, degenerative diseases of the heart, anemia, sensitive and weak nervous system, lack of pep and vitality, tired mind, poor memory, and irritability; that the articles, because of their phosphorus content, would prevent digestive and cardiac disorders, headaches, brain and nerve exhaustion with physical and mental break-down, disturbed protein metabolism, sugar in blood, prolonged and profuse menstruation, and sexual weakness and impotence in the male; that the articles, because of their sulfur content, would prevent contraction of the bladder, frequent urination, crampy sensation in pubic region, impaired digestive function, puffiness, spasmodic crampy pain during menstrual function; that the articles, because of their potassium content, would prevent periodic headaches, wandering pain, dry skin, chilliness with fever, and weak, flabby and atrophied muscles, would promote healing of leg ulcers, and would prevent constipation, flatus, miscarriage with diarrhea and other forms of colitis, and disturbed circulation; that the articles, because of their magnesium content, would keep digestive organs clean and elastic and would stimulate their functional activity, would keep fluids and tissues of the body alkaline, cool and soothe brain and nervous system, assist in keeping calcium phosphate from forming deposits, neutralize acid reactions in brain and nervous system, stimulate and increase functional activity of nerves and brain, and prevent tense and hot nervous system, congestive headaches, weak eyes, poor sight, greasy face and scalp, impaired digestion, constipation, putrefaction in the large intestine, indican in the urine, catarrh, cold, and la grippe or flu; that the articles because of their chlorine content, would benefit metabolism and cell growth, promote peristaltic action, act on the muscular system through the motor nerves, neutralize poison

in stomach and intestine, and excite sex function, and prevent sluggish and indifferent brain function, vertigo, cold hands and feet, poor appetite, indigestion, constipation, sore mouth, foul breath, belching, flatulence, boils, pus formation in small wounds, skin eruptions, and loss of hair; that the articles, because of their sodium content, would exert a beneficial influence on every function of the body and prevent suffering from many and varying symptoms of the body and mind, neuritis, arthritis, headaches, intestinal disorders, heart weakness, enlarged liver spleen, lack of tone in various organs causing prolapsus or ptosis, and flabby and weak arms and legs; that the articles, because of their iron content, would prevent deficiency of oxygen in blood and lack of hemoglobin, and would prevent pale skin, loss of pep, tone, strength, vitality, and charm, colds and catarrhal conditions, infectious diseases, indigestion, nausea, sleeplessness, and night sweats; that the articles, because of their iodine content, would have a beneficial effect on brain function and the nervous system, would neutralize toxins arising from meat and albuminous products that may be decomposing in the intestines, and would increase oxidation of metabolic byproducts and fats, guard the body against destructive action of decomposition products, act as health officer, and keep the body clean; that the articles, because of their fluorine content, would prevent brittle, soft, and easily fractured bones, dry joints, slow healing of bone fractures, crumbling nails, and teeth which will corrode and decay; that the articles, because of their silicon content, would prevent multiple neuritis, brain starvation, timidity, loss of confidence, fear, dry scalp or scabby skin, dry lips with scabby eruptions, ringworm, eczema, scabs behind ears, abscesses at root of teeth, canker sores on lips and gums, weak bladder, and diarrhea or constipation; that the articles, because of their manganese content, would prevent tendency to apoplexy and paralysis, poor eyesight, erratic taste, loss of appetite, distention, flatulence, drowsiness in daytime, and restlessness or sleeplessness at night; that the articles would prevent mineral starvation and the many diseases resulting therefrom; and that they would help keep one well, restore tissue balance and eliminate urates, cleanse the kidneys and balance the Ph of body fluids, support all nutritional and recuperative therapies by a marked action as a catalyst, induce restful sleep and balance the nervous system, build tissue, create appetite, stop wasting diseases, and equalize vascular tension.

Further misbranding, Section 502 (a), certain statements in the labeling of the *No. 41*, namely, in the accompanying leaflet entitled "Seroyal-Bulletin," were false and misleading since the statements were contrary to fact. The statements represented and suggested that the article would have a beneficial effect on brain function and the nervous system, would neutralize toxins arising from meat and albuminous products that may be decomposing in the intestines, would increase oxidation of metabolic byproducts and fats, would guard the body against destructive action of decomposition products, would act as a health officer, and would keep the body clean.

Further misbranding, Section 502 (e) (1), the labels of the *No. 12, Juglins Nigra Tea*, and *Equisetum Hiemale Tea* failed to bear the common or usual name of the articles, namely, alfalfa, black walnut, and horsetail or shave grass, respectively.

DISPOSITION: October 2, 1951. Default decree of condemnation and destruction.

3676. Misbranding of Mile Deep mineral water. U. S. v. Jesse L. Rogers. Plea of nolo contendere. Sentence of 6 months' imprisonment suspended and defendant placed on probation for 6 months. (F. D. C. No. 30577. Sample No. 3052–K.)

INFORMATION FILED: June 18, 1951, District of Columbia, against Jesse L. Rogers, president of R. & S. Nutrients, Inc., Washington, D. C.

ALLEGED VIOLATION: On or about July 24, 1950, the defendant sold and delivered in the District of Columbia a quantity of *Mile Deep mineral water*, a drug; and between the approximate dates of July 24 and August 23, 1950, the defendant caused to accompany the drug a number of booklets entitled "Mineral Water from the Mile Deep Maple Well."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklet entitled "Mineral Water from the Mile Deep Maple Well" were false and misleading. The statements represented and suggested that a spoonful daily of the article would provide the user with good health; that the article would be efficacious in the treatment of sores on the face and body; that the calcium chloride content of the article enabled it to produce red blood; that its magnesium content acted as a cleansing agent; that many major diseases are caused by deposits of inorganic minerals in the body (joints, blood vessels, etc.), and that the article would put such minerals to work for health; that it would be efficacious in preventing stiffening and excess depositing of minerals in the tissues, and thus would be efficacious to prevent or relieve arthritis, high blood pressure, or other ailments; that it would be efficacious to render water-soluble the deposited or crystallized minerals and metals in and on the tissues, making these more flexible; that it would be efficacious to cause the body to assimilate minerals deposited in or on the tissues; that it would be efficacious to dissolve tissue waste and thus benefit the sick; that it would be efficacious to prevent poor health as a result of metal or mineral poisoning due to trace elements ingested in larger quantities than the body can use; that it was a wonderful aid to arthritic patients by reason of its ability to break down excessive calcium deposits in the joints; that it would be efficacious to move poisons in the body; that it would remove the cause of high blood pressure, gallstones, and scores of other ailments; that it would be effective to restore health and to provide the necessary elements for the structure and vitality of the organs; that it would be efficacious to maintain health and strength by supplying inorganic salts; that it would be effective in curing long standing chronic diseases brought on by overdosing and excessive use of such medicines as quinine, mercury, etc.; that it would be efficacious to remedy the chronic forms of nervous debility, rheumatism, asthma, anemia, diabetes, goiter, organic heart disease, neuralgia, paralysis, varicose veins, catarrh, and dropsy; that by reason of its content of sulfate of calcium, it would be efficacious to prevent cell disintegration and suppuration, and would be effective in the third state of all suppurative processes, including catarrhs, lung troubles, boils, carbuncles, ulcers, abscesses, pimples and pustules of the face, and all cases of true suppuration; that by reason of its content of chloride of potash, it would be efficacious in the treatment of glandular swelling, discharges or expectoration of a thick, white,

fibrous consistency, white or grey exudations, and would be excellent in catarrhal conditions with those symptoms; that it would be effective to remedy croup, diphtheria, dysentery, and pneumonia, and would be effective to control plastic exudation; that by reason of its content of chloride of soda, it would be effective to act on the blood, liver, spleen, and every mucous membrane of the body; that by reason of its content of chloride of soda, it would be efficacious in the treatment of headache, toothache, faceache, stomach ache, vomiting of water and mucus, catarrhal affections of mucous membranes with secretion of transparent, frothy, watery mucus, small watery blisters or blebs on the skin, diarrhea, slimy, transparent stools, inflammation of the eyes, and leucorrhea; that it would be efficacious to wash the tissues and eliminate drugs from the system; that by reason of its silica content, it would be effective to promote suppuration and ripen abscesses; that it would be effective to cure chronic, gouty, rheumatic affections and restore suppressed foot-sweats, thus indirectly remedying diseases resulting from suppression of foot-sweat, such as amblyopia, cataract, paralysis, etc.; that it would be effective to prevent atrophy; that it would favorably affect the central and peripheral nervous systems, and thus it would be efficacious in the treatment of languor, sleepiness, anxious dreams, nervous irritability, depression, headaches, trembling, and paretic symptoms; by reason of its chlorine content, it would be effective to aid in the regulation and stimulation of muscular action, would be effective to aid digestion, and would activate; that by reason of its magnesium content, it would favorably affect muscular activity, nerve stability, and bone structure, and would have a laxative effect; that by reason of its sodium content, it would be efficacious to maintain normal heart action; that it would be effective to prevent rapid disintegration of cell tissues; that by reason of its radium content, it would have beneficial effects; that it would be effective to render the user free from all symptoms of rheumatism; that it would be efficacious to remedy diabetes mellitus, and that where the pancreatic gland is not too much destroyed, it would be efficacious to restore the gland to its normal functions; that it would be efficacious in the treatment of tuberculosis; that it would be efficacious in the cure of high blood pressure; that it would be efficacious in the treatment of severe cases of laryngitis accompanied by an ulcerated mouth; that it would be efficacious to remedy unbearable pain in the legs; that it would be effective in the treatment of pyorrhea; that if used as a rinse for the mouths of children, it would be efficacious to decrease their aches and pains and ill health caused by pyorrhea; that it would be efficacious to relieve external itching; that it would be efficacious to give quick recovery from an alcoholic "binge"; that it would be efficacious in the treatment of hemorrhoids; that it would be efficacious in the treatment of the common cold, la grippe, and bronchitis; that it would be efficacious to produce a healthy pink color in the face; that it would be efficacious in the treatment and cure of disease conditions in cases of all sorts, such as hives of long standing, high blood pressure, diabetes, ulcers of the stomach, arthritis, leg pains, kidney and bladder trouble, and loss of appetite, where no response had resulted from the usual medical and hospital treatment, various diets, and/or drugless treatments; that it would be efficacious to enable the diabetic to abandon the use of insulin; that it would be more effective in getting the average patient back toward health than vitamins; that when applied externally, it would be efficacious in the treatment of ulcers; that it would supply mineral salts which would not be obtainable in food because of depleted soils and cooking; that it would be efficacious in the treatment and cure of duodenal and pyloric ulcers;

that it would be efficacious in the treatment and cure of gastric ulcers, and would render the user stronger and more buoyant; that it would supply energy and pep, and would make the user feel like one, half his age; that it would be efficacious in the treatment of dizzy spells and weakened condition, and would enable the user to sleep; that it would be efficacious in the cure of nausea resulting from a nervous stomach, and would be efficacious to shorten the course of la grippe and the "grippy" cold and "achy" feeling accompanying that condition; and that it would be efficacious to prevent the loss of sense of smell or taste during a cold. The article would not be efficacious to accomplish and would not accomplish, nor be effective to accomplish, the results and purposes represented and suggested.

DISPOSITION: December 7, 1951. The defendant having entered a plea of nolo contendere, the court sentenced him to prison for 6 months, but suspended the execution of the sentence and placed him on probation for 6 months.

3677. Misbranding of Cal-O-Min "D" tablets and Cal-O-Min Jr. tablets. U. S. v. 8 Cases, etc. (F. D. C. No. 31708. Sample Nos. 11535–L, 11536–L.)

LIBEL FILED: September 20, 1951, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about April 3 and 5, 1951, by Cal-O-Min, Inc., from Wichita, Kans.

PRODUCT: 8 cases, each containing 12 100-tablet bottles, and 2 cases, each containing 12 200-tablet bottles, of *Cal-O-Min "D" tablets*, and 5 boxes, each containing 24 10-tablet vials, of *Cal-O-Min Jr. tablets*, at McMinnville, Tenn. Leaflets entitled "For Your Health's Sake" were shipped with the product.

LABEL, IN PART: (Bottle) "Cal-O-Min 'D' (10 grains) * * * Analysis $CaCO_3$, Calcium Carbonate 99.3% Fe_2O_3, Iron Oxide .007% MgO, Magnesium Oxide .027% $MgCO_3$, Magnesium Carbonate .486% Vitamin 'D' per Tablet 250 U. S. P."; (vial) "Cal-O-Min Jr. * * * Contents: Calcium Carbonate (Crystalline Form), Iron Oxide, Mag. Carb. Directions: 1 or 2 Tab."

NATURE OF CHARGE: *Cal-O-Min "D" tablets.* Misbranding, Section 502 (a), certain statements in the leaflets were false and misleading. These statements represented and suggested that the article was an adequate and effective treatment for rash, hives, pimples, eczema, asthma, bowlegs, anemia, arthritis, bad blood, rickets, bad teeth, nervousness, fatigability, rheumatism, hot flashes, nail biting, heartburn, gas pains, hay fever, indigestion, allergies, constipation, brittle nails, round shoulders, assaultiveness, incorrigibility, swollen glands, defective veins, heart ailments, non-adaptability, poor complexion, defective vision, bony deformities, defective intestines, defective arteries, lack of personality, migraine headaches, neuralgic headaches, withering with age, poor hair texture, rheumatic fever pains, leg and muscle cramps, and reduced resistance to disease; that the article would improve the health, complexion, and personality; that it would enable the user to avoid deformities, disease, and suffering; that it is required for the perfect digestion of all foods; that it is the dominant nerve controller and regulates nerve action; that it coordinates other mineral elements and corrects their disturbances; that it affects the cell formation of all living things and vitalizes cell life; that it governs the rhythmic beat of the heart; that it increases strength and pulsation of the heart; that it corrects defects in blood coagulation; that it strengthens the walls of arteries, veins, and intestines; that it increases resistance to fever and disease; that it governs contractility of the muscles; that it promotes intelligence, will power, and ability to concentrate; that it supplies calcium, necessitated by the alleged

fact that many of our foods are being raised on depleted soils that no longer supply us with sufficient calcium; and that there are many symptoms of ill health due to calcium deficiencies in our daily diet, and that many morbid conditions and actual diseases may result. The article would not be effective for the purposes represented, suggested, and implied.

Cal-O-Min Jr. tablets. Misbranding, Section 502 (a), certain statements on the vial label and on a display card entitled "Cal-O-Min Jr.," enclosed in the box and on the wrapper around the box, were false and misleading. These statements represented and suggested that the article was an adequate and effective treatment for indigestion and nervousness, and that it would be effective to enable the users to enjoy meals and to improve their health. The articles would not be effective for those purposes.

The *Cal-O-Min Jr. tablets* were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 18, 1952. Default decree of condemnation and destruction.

3678. Misbranding of Lipitrons capsules. (F. D. C. No. 31988. Sample No. 15706–L.)

LIBEL FILED: November 6, 1951, District of Kansas.

ALLEGED SHIPMENT: On or about September 20 and October 4, 1951, by Vitamin Industries, Inc., from Omaha, Nebr.

PRODUCT: 48 100-capsules bottles of *Lipitrons capsules*, together with a poster entitled "If You Are Over 35" and a newspaper tear sheet beginning with the phrase "If You Are More Than 35 Years Old," at Topeka, Kans.

LABEL, IN PART: (Bottle) "Guardian 100 Caplets Lipitrons High Potency Lipotropic Formula Each Caplet Contains: Vitamin B_1 15 mgm. Vitamin B_2 6 Mgm. Vitamin C 50 mgm. Niacinamide 30 mgm. Calcium Pantothenate 3 mgm. Vitamin B_6 0.5 mgm. Desiccated Whole Liver 175 mgm. Dried Debittered Yeast 175 mgm. Choline Dihydrogen Citrate 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm. Iron as Ferrous Gluconate 30 mgm. Folic Acid 0.1 mgm. Vitamin B_{12} (oral Conc.) 3 mcg."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "High Potency Lipotropic Formula" was false and misleading, and the label statement "Each Caplet Contains * * * Choline Dihydrogen Citrate 20 mgm. Inositol 20 mgm. dl-Methionine 20 mgm." was misleading as applied to the product, which did not possess significant lipotropic properties, and which when used as directed, provided inconsequential amounts of inositol, choline, and dl-methionine.

Further misbranding, Section 502 (a), certain statements in the poster entitled "If You Are Over 35" were false and misleading. These statements represented and suggested that the product would be effective to relieve that "growing old feeling" and to help one to enjoy life, whereas it was not effective for the purposes stated.

The libel alleged further that the article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce since the following statements in the newspaper tear sheet were false and misleading: "If You Are More Than 35 Years Old If you are getting that 'Growing Old' Feeling Science Has Now Found How To Fight That Feeling of 'Growing Old' Lipitrons For You if You Feel Tired and Weak and Run-Down! For You to

Help You Recapture Lost Vitality and Strength! For You to Combat Nervousness, Lack of Vigor and Energy! * * * Lipitron Is a True 'Geriatric' Formula Lipitron contains in each caplet important amounts of Inositol, Choline and dl-Methionine, the lipotropic factors * * * the factors so tremendously concerned in the new field of 'Geriatrics' . . . the science of treatment of advancing age. To Help You Enjoy Life Again! Lipitrons attack true basic causes of the Tired Feeling. Poor Appetite, Loss of Weight and Strength, Insomnia or Sleeplessness, and other symptomatic conditions of deficiencies in your nutritional intake that may be directly responsibile for your condition. Yet, you too, can really begin to Enjoy Life Again. Here is What Lipitrons Do For You If You are now past your youth . . . if you have been blaming your tired, weak feeling on 'just getting old' . . . you are not taking advantage of the near miraculous benefits that vitamin and nutrition science has developed to help you. In the Vitamin field, Vitamin scientists have achieved new heights in formulation. Lipitron is designed specifically to help you overcome the deficiencies that help drag you down and down. Thousands have found thrilling new hope when the signs of advancing age were due to lack of Thiamin, Riboflavin, Niacinamide and Vitamin C in their systems. They've discovered a whole new world of buoyant energy, vitality and strength by relieving and overcoming the basic causes of their nutritional deficiencies * * * Start Today! Know The Joy of Feeling Your 'Level Best'." The product was not effective for the purposes stated, and, when used as directed, it would not supply important amounts of inositol, choline, and dl-methionine.

DISPOSITION: January 14, 1952. Default decree of condemnation and destruction.

3679. Misbranding of maté, toasted maté, and Herva-Maté. U. S. v. 17 Cases, etc. (F. D. C. No. 31352. Sample Nos. 9033-L, 9034-L.)

LIBEL FILED: On or about July 24, 1951, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about October 9, 1948, by the National Matte Institute of Brazil, from New York, N. Y.

PRODUCT: 17 50-pound cases of *maté*, 2 50-pound cases of *toasted maté*, and 56 8-ounce packages of *Herve-Maté* at Appleton, Wis., in possession of Merritt R. Miller & Sons Co. In addition, a number of folders bearing on the front panel a picture of Indians, a slain leopard, and a small tree, and one folder headed "National Matte Institute of Brazil," had been shipped by the National Matte Institute of Brazil, from New York, N. Y., on or about October 19, 1948.

RESULTS OF INVESTIGATION: The 56 packages of the product had been repacked by the consignee from the 17-case lot and labeled, in part, "Herva-Maté." The consignee had on hand 3,000 labels intended for use in repackaging the article, 100 envelopes, 5,000 folders entitled "The Message of Maté," 1,000 circular letters headed "Merritt R. Miller" and addressed to "Dear Friend," a number of leaflets entitled "Keep Well with Herva Maté," and a number of circulars headed "A Proposition Where You Do Not Beg Nor Coax for Orders," all of which labeling contained statements relating to the articles.

LABEL, IN PART: (17 cases) "Instituto Nacional Do Mate Merritt R. Miller & Sons Co. Appleton, Wisconsin"; (2 cases) "Product of Standard Black Matte Tea Toasted Matte Merritt R. Miller & Sons Co. Appleton, Wisconsin"; (folder headed "National Matte Institute of Brazil") "per 100 grams * * * Vitamin A 1800 I. U. (mostly as beta-carotene) Vitamin B_1 57 I. U. Vitamin

B_2 (G) 62 gamma riboflavin (24 Sherman-Bourquin Units) Vitamin C 135 I. U."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the folder headed "National Matte Institute of Brazil," relating to the products labeled "maté" and "toasted maté," were false and misleading. These statements represented and suggested that the articles were effective to restore health, to maintain health, and to restore exhausted energies and the strength of youth; that they were tonics; that they would have no harmful reactions; that they would enable one to do a wonderful amount of work on little food; that they would facilitate digestion without disturbing the sleep; that they would help the functioning of the intestines and kidneys; and that when used as directed, the articles would supply significant amounts of vitamins A, B_1, B_2 (G), and C. The articles were not effective for the purposes stated and implied; they were not capable of fulfilling the promises of benefit made for them; and when used as directed, they would not supply significant amounts of vitamins A, B_1, B_2 (G), and C. The *maté* and the *toasted maté* were misbranded in the above respects when introduced into and while in interstate commerce.

The articles, including the portion labeled "Herva-Maté," were misbranded under Section 502 (a), in that certain statements in the labeling, namely, the package label, the sample envelopes, the folders entitled "The Message of Maté," the circular letters headed "Merritt R. Miller," the leaflets entitled "Keep Well with Herva Maté," and the circulars headed "A Proposition Where You Do Not Beg Nor Coax for Orders," were false and misleading. These statements represented and suggested that the articles were effective for health and vigor; that they were effective to overcome nervousness; that they were effective to induce sound, refreshing sleep; that they were good for the digestion; that they would avert hunger pangs; that they would be effective in weight reduction; that they would supply vigor and endurance; that they would supply many minerals vital to the body, and three important vitamins; that they would be of value in the treatment of nervousness, digestive difficulties, sleeplessness, run-down condition, loss of vigor, etc.; that they would prevent hunger sensation or discomfort when used instead of food; that they would make a healthful beverage; that they would be useful in correcting bodily weakness and maintaining bodily vigor; that they would give ruggedness; that they would sustain one in long rides under summer sun and in winter cold; that they would keep the kidneys healthy, the liver regular, and the stomach "at peace"; that they would tend to prevent kidney and liver ailments; that they would cause stomach complaints due to overloading to disappear; that they would still the pangs of hunger; that they would serve fleshy people as a food substitute; that they would be effective in digestive ailments; that they would be beneficial in those cases in which tea and coffee might be harmful; that they would be directly helpful in digestion and to help tone up suffering organs; that they would keep organs that are in good condition in health; that their chlorophyll content would act as a tonic; that they would supply albumen and glycol; that they would cause one who is feeling downcast all the time, has backaches, worries about the future, does not sleep well, is "nervous as a cat," whose digestion is out of shape, to feel better, and if their use is continued, they would effect a cure; that they would enable a half person to be a person plus; that they would be effective for underweight; that they would supply digestive stimulation; that they would induce the digestion of the more nourishing foods; that they would increase bodily vigor; that they would help the body help itself; that they would be

effective in the relief of those who are suffering from our common ailments; that they would improve health and give one ability to eat almost everything without distress; that they would effect all around health improvement; that they would enable one to keep well; that they would supply good health to the sick, vigor to the weak, and slimness to the stout, add joy to life, and make natural beauty; that they would build resistance against colds; that they would benefit those afflicted with stomach, kidney, and liver complaints; that they would keep an 85-year-old person well and hearty; that they would give relief from nervousness and enable one to sleep soundly; that they would nullify over-indulgence in any form and afford healing; that they would enable one to live several days without solid food; that they would act directly on the muscles without affecting the nerve centers; that they would act as a brain tonic; that they would give force and energy and constitute a reservoir of vitality; that they belong in the first rank of economic foods, because they are digestive, stimulating assimilation, and have a laxative, sudorific action; that they would be effective for weak people; that they do not act strongly on the nerves but soothe and quiet them; that they leave no disagreeable aftereffects; that they do not cause insomnia; that they are useful for those who suffer from debility or neurasthenia; that they would preserve beauty; that they had restorative qualities; that they would strengthen the body, brain, and nerves; that they would enable one to gain or regain grand abounding health; that three out of every five adults need the article; that they confer upon all great benefit; that in certain illnesses and body conditions, they bring sure relief; and that they are a first-grade nutrient. The articles were misbranded in the latter respects while held for sale after shipment in interstate commerce.

DISPOSITION: January 29, 1952. Default decree of condemnation and destruction.

3680. Misbranding of Fenco Sinus Relief. U. S. v. 6 Cartons * * *. (F. D. C. No. 30358. Sample No. 48833–K.)

LIBEL FILED: December 29, 1950, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 20, 1950, by the United Chemical Co., from Newark, N. J.

PRODUCT: 6 cartons, each containing 18 4-ounce packages, of *Fenco Sinus Relief* at Wilkes-Barre, Pa.

LABEL, IN PART: (Package) "Fenco Sinus Relief Containing Sodium Bicarbonate, Sodium Chloride, Sodium Borate, Zinc Sulfate, Menthol, Eucalyptol and Flavoring."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not effective in the treatment of the conditions and diseases stated and implied and was not capable of fulfilling the promises of benefit described: (Package label) "Sinus Relief * * * Individuals with sinus trouble continue to have discomfort so long as the infected material is not draining. This disturbance is usually relieved by using Fenco as directed. In severe cases use Fenco six or eight times a day until results have been obtained. Do not be alarmed if you feel a slight burning sensation when first using Fenco. This is due to inflammation and will disappear after a few applications" and (leaflet enclosed in each package) "Sinus Relief * * * Very often when your nose is stopped up, the infection backs through these openings into the sinuses. Then

they become inflamed and close up, and sometimes even fill with pus. The inflammation gives you the headache, and the pus, if it stays there, can finally get into your blood stream and cause rheumatism and other troubles, such as bronchitis, digestive disturbance, arthritis, and impairment to eyesight * * * When used as directed Fenco should give prompt relief in cases of Sinus, Catarrh, Hay Fever, Head Colds and Rose Fever. Fenco opens up the clogged sinuses and clears the nasal passages of congestion and pus without drying out the membrane of the nose and throat; relieves the inflammation and lets air pass in and out of Sinus caves in a normal way * * * keep sinus and head cold attacks away * * * Nasal congestion and sneezing misery are very common complaints today, and whether caused by sinus, catarrh, hay fever, rose fever or head colds, clogged nostrils succumb to Fenco treatments. 'It clears out the head and keeps it clean' * * * Join the many people who, after suffering from agonizing Sinus-clogged nostrils, head colds and sneezing misery, tell of blessed relief after using Fenco * * * Fenco your head Every Day and keep Sinus and Head Cold attacks away! * * * 'I have suffered from Chronic Sinusitis for the past 18 years. This type of sinus affliction evidenced itself in constant nasal congestion, continuous coughing-up of phlegm and occasional severe headaches. I am most pleased to report, that although I have used "Fenco" for only 2 weeks, the improvement in my condition is almost unbelievable. For the first time in many years I am able to breathe through my nose without restriction. Moreover the post nasal drip has been retarded and my headaches have disappeared.' "

DISPOSITION: December 20, 1951. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3661 to 3680

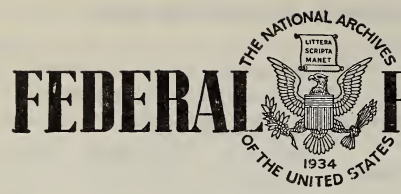
PRODUCTS

[1] (3663) Injunction issued. Contains opinions of the courts.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3663) Injunction issued. Contains opinions of the courts.

U. S. GOVERNMENT PRINTING OFFICE: 1952



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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3681–3700

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*
WASHINGTON, D. C., *August 7, 1952.*

CONTENTS*

*For presence of a habit-forming narcotic without warning statement, see Nos. 3681–3683; omission of, or unsatisfactory, ingredients statements, Nos. 3682–3686, 3696; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3681–3686; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3683–3686.

213287—52——1

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3681. Misbranding of Seconal Sodium capsules and methyltestosterone tablets. U. S. v. Norton Drug Stores, Inc., and Theodore Cibolski and Edward T. Kanaley. Pleas of guilty. Corporation fined $60, Theodore Cibolski fined $50, and Edward T. Kanaley fined $10, together with costs (F. D. C. No. 31262. Sample Nos. 70434–K, 70514–K, 70515–K, 89784–K, 89787–K, 90017–K.)

INFORMATION FILED: November 16, 1951, District of Kansas, against Norton Drug Stores, Inc., Manhattan, Kans., and Theodore Cibolski, secretary of the corporation, and Edward T. Kanaley, an employee.

INTERSTATE SHIPMENT: On or about February 23 and July 10, 1950, from the States of Missouri and New Jersey, of quantities of *methyltestosterone tablets*, and on or about July 13, 1950, from the State of Missouri, of a quantity of *Seconal Sodium capsules*.

ALLEGED VIOLATION: On November 6, 9, 14, 20, and 21, 1950, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The Norton Drug Stores, Inc., was charged with causing the acts of repacking and sale of the drugs involved in each of the six counts of the information; in addition, Theodore Cibolski, in each of five counts of the information, and Edward T. Kanaley, in one count, were charged with causing the acts charged in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: March 7, 1952. Pleas of guilty having been entered, the court fined the corporation $60, Theodore Cibolski $50, and Edward T. Kanaley $10, together with costs.

3682. Misbranding of Seconal Sodium capsules and methyltestosterone tablets. U. S. v. Lee T. King (Kings Drug Store). Plea of guilty. Fine of $80, plus costs. (F. D. C. No. 31265. Sample Nos. 55998–K, 70413–K, 70414–K, 70516–K, 70721–K, 89783–K, 89786–K, 90019–K.)

INFORMATION FILED: November 16, 1951, District of Kansas, against Lee T. King, trading as Kings Drug Store, Manhattan, Kansas.

INTERSTATE SHIPMENT: From the States of Indiana, New Jersey, and Missouri, into the State of Kansas, of quantities of *Seconal Sodium capsules* and *methyltestosterone tablets*.

ALLEGED VIOLATION: On or about October 3, 16, 24, and 25, and November 6, 9, 14, and 20, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to

be repacked and sold without a physican's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *methyltestosterone tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: March 7, 1952. A plea of guilty having been entered, the court fined the defendant $80, together with costs.

3683. Misbranding of Seconal Sodium capsules and Dexedrine Sulfate tablets. U. S. v. Joe G. Levin and Carl D. King. Pleas of nolo contendere. Fines of $250 against Defendant Levin and $100 against Defendant King, and each defendant placed on probation for 1 year. (F. D. C. No. 30584. Sample Nos. 82181–K, 82193–K, 93106–K, 93111–K, 93119–K, 93242–K.)

INFORMATION FILED: July 18, 1951, Northern District of Georgia, against Joe G. Levin, a partner in the partnership of the Owl Drug Co., Atlanta, Ga., and against Carl D. King, a pharmacist for the partnership.

INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Georgia, of quantities of *Seconal Sodium capsules* and *Dexedrine Sulfate tablets*.

ALLEGED VIOLATION: On or about October 16 and November 1, 2, 13, 15, and 22, 1950, while the drugs were being held for sale at the Owl Drug Co. after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

Joe G. Levin was charged with causing the repacking and sale of the drugs involved in three of the counts, and Carl D. King was charged with causing the repacking and sale of the drugs involved in the remaining three counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (e) (1), the repackaged *Dexedrine Sulfate tablets* failed to bear a label containing the common or usual name of such drug.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: March 7, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $250 against Defendant Levin and a fine of $100 against Defendant King and placed each defendant on probation for 1 year.

3684. Misbranding of Dexedrine Sulfate tablets. U. S. v. Cicero's Drug Store and Sherwood V. Roark. Pleas of nolo contendere. Each defendant fined $250. (F. D. C. No. 30622. Sample Nos. 21037–L, 21045–L, 21049–L, 21951–L.)

INFORMATION FILED: September 12, 1951, Northern District of Texas, against Cicero's Drug Store, a partnership, Grand Prairie, Tex., and Sherwood V. Roark, a partner.

INTERSTATE SHIPMENT: From the State of Pennsylvania into the State of Texas, of quantities of *Dexedrine Sulfate tablets.*

ALLEGED VIOLATION: On or about February 22 and March 2 and 13, 1951, while the drug was being held for sale at Cicero's Drug Store after shipment in interstate commerce, the defendants caused a number of the tablets to be repackaged and sold without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the labeling of the repackaged tablets bore no directions for use; Section 502 (b) (1), the repackaged tablets involved in three of the four sales failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (1), the repackaged tablets involved in one of the sales failed to bear a label containing the common or usual name of the drug.

DISPOSITION: February 28, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $250 against Cicero's Drug Store and $250 against Sherwood V. Roark.

3685. Misbranding of amphetamine sulfate tablets. U. S. v. Hardy McClary. Plea of guilty. Sentence of 1 year in prison and fine of $500; execution of prison sentence suspended and defendant placed on probation for 1 year. (F. D. C. No. 30625. Sample Nos. 21012–L, 21013–L.)

INFORMATION FILED: September 12, 1951, Northern District of Texas, against Hardy McClary, Dallas, Tex.

INTERSTATE SHIPMENT: On or about March 5, 1951, from the State of New Jersey into the State of Texas, of a quantity of *amphetamine sulfate tablets.*

ALLEGED VIOLATION: On or about March 23 and 24, 1951, while the drug was being held for sale after shipment in interstate commerce, various quantities of the drug were repacked and sold by the defendant without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; Section 502 (e) (1), the drug failed to bear a label containing the common or usual name of the drug; and Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: February 22, 1952. The defendant having entered a plea of guilty, the court sentenced him to imprisonment for 1 year and fined him $500. The

court ordered, however, that the execution of the sentence of 1 year be suspended upon payment of the fine.

The fine was paid on February 25, 1952, and on February 28 the sentence of 1 year in prison was suspended, and the defendant was placed on probation for 1 year.

3686. Misbranding of testosterone. U. S. v. Joseph C. Mills. Plea of guilty. Defendant sentenced to 7 days in prison. (F. D. C. No. 32745. Sample No. 28263–L.)

INFORMATION FILED: January 21, 1952, District of Arizona, against Joseph C. Mills, Tucson, Ariz.

ALLEGED SHIPMENT: On or about January 25, 1951, from the State of Arizona into the State of California, of a number of unlabeled ampuls of testosterone.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, and against unsafe dosage and method and duration of administration, and such manner and form, as are necessary for the protection of users, in that the article was for use by injection into or through the skin and contained 24.7 milligrams of testosterone (male sex hormone) per cubic centimeter; and the labeling of the article failed to warn that its use by females may have masculinizing effects such as the development of excessive hair growth on the face and body, coarsening of the voice, acne, suppression of normal menstruation, enlargement of the clitoris, and decreasing the size of the breasts; that its use by males with carcinoma of the prostate may result in acceleration of the malignant growth; and that its use by children may induce precocious puberty.

DISPOSITION: March 12, 1952. A plea of guilty having been entered, the court imposed a sentence of 7 days in prison.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3687. Adulteration of celandine herb. U. S. v. 6 Bales * * *. (F. D. C. No. 32678. Sample No. 12093–L.)

LIBEL FILED: February 19, 1952, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 5, 1951, from Jersey City, N. J.

PRODUCT: 6 bales, each containing 162 pounds, of *celandine herb* at Cincinnati, Ohio.

LABEL, IN PART: "Imported Great Celandine Herb * * * for Manufacturing or Repacking Use Only."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects, insect fragments, and rodent hairs. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: March 19, 1952. Default decree of condemnation and destruction.

3688. Adulteration of psyllium husks (Plantago). U. S. v. 113 Bags, etc. (F. D. C. No. 31166. Sample Nos. 23106–L, 23107–L.)

LIBEL FILED: June 1, 1951, Eastern District of New York.

ALLEGED SHIPMENT: On or about September 23 and October 20, 1950, from Sidhpur, India.

PRODUCT: 232 bags of *psyllium husks* (Plantago) at Brooklyn, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance by reason of the presence of insects. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: June 22, 1951. Prentiss Drug & Chemical Co., Inc., Brooklyn, N. Y., having appeared as claimant, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, by fumigating, cutting, sifting or blowing, and destruction of the unfit portion, under the supervision of the Food and Drug Administration. Salvage operations resulted in the release of 18,883 pounds of the product. The remaining 2,200 pounds were denatured and destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3689. Adulteration and misbranding of belladonna tincture and paregoric. U. S. v. Ormont Drug & Chemical Co., Inc. Plea of guilty. Fine, $525. (F. D. C. No. 31267. Sample Nos. 74838–K, 91904–K, 91919–K, 92268–K, 22798–L to 22800–L, incl.)

INFORMATION FILED: January 7, 1952, Eastern District of New York, against Ormont Drug & Chemical Co., Inc., Long Island City, N. Y.

ALLEGED SHIPMENT: On or about June 21, September 8, October 13 and 19, November 9 and 16, and December 20, 1950, from the State of New York into the States of New Jersey and Connecticut.

LABEL, IN PART: "Ormont * * * Belladonna Tincture U. S. P. (Tinctura Belladonnae)" and "Ormont * * * Paregoric U. S. P. Tinctura Opii Camphorata."

NATURE OF CHARGE: Adulteration, Section 501 (b), both products were represented to be drugs, the names of which are recognized in the United States Pharmacopeia, an official compendium, and their strength differed from the standards set forth in such compendium; and their differences in strength from the official standards were not stated on their labels. The *belladonna tincture* yielded more than 33 milligrams of the alkaloids of belladonna leaf per 100 cc., and the *paregoric* yielded more than 45 milligrams of anhydrous morphine per 100 cc.

Misbranding, Section 502 (a) the statements "Belladonna Tincture U. S. P." and "Paregoric U. S. P." borne on the labels of the respective products were false and misleading since the statements represented and suggested that the drugs were of the strength established in the United States Pharmacopeia, whereas they were not of such strength in that the *belladonna tincture*

yielded alkaloids of belladonna leaf in excess of the maximum provided by the Pharmacopeia, and the *paregoric* yielded anhydrous morphine in excess of the maximum so provided.

DISPOSITION: February 13, 1952. A plea of guilty having been entered on behalf of the defendant corporation, the court imposed a fine of $525.

3690. Adulteration and misbranding of conjugated estrogens. U. S. v. 11,288 Tablets * * *. (F. D. C. No. 32429. Sample No. 11619–L.)

LIBEL FILED: January 11, 1952, Northern District of Ohio.

ALLEGED SHIPMENT: On or about April 9, 1951, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

PRODUCT: 24 bottles containing a total of 11,288 tablets of *conjugated estrogens* at Cleveland, Ohio. Analysis showed that the product contained a total amount of estrogenic steroids calculated as 0.71 mg. of sodium estrone sulfate per tablet.

RESULTS OF INVESTIGATION: The tablets were contained in a drum when shipped in interstate commerce, and after receipt by the consignee, they were repackaged into bottles and relabeled.

LABEL, IN PART: (Drum) "Lot No. 7971 30,000 Sugar Coated Estrogen 1.25 Mg. Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the following statement on the drum label was false and misleading as applied to an article whose equivalent in biological activity was less than that declared: "Each tablet contains: Naturally-occurring water-soluble conjugated estrogens equivalent in biological activity to 1.25 mg. of sodium estrone sulfate * * *."

DISPOSITION: March 11, 1952. Default decree of condemnation and destruction.

3691. Adulteration and misbranding of Beferm Elixir. U. S. v. 4 Bottles * * *. (F. D. C. No. 32452. Sample No. 10712–L.)

LIBEL FILED: January 28, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 26, 1951, from Woodworth, Wis.

PRODUCT: 4 1-gallon bottles of *Beferm Elixir* at Chicago, Ill. Analysis showed that the product contained approximately 62 percent of the declared amount of vitamin B_1 and approximately 60 percent of the declared amount of vitamin B_{12}.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 25 mg. of vitamin B_1 and 10 mcg. of vitamin B_{12} in each fluid ounce.

Misbranding, Section 502 (a), the label statement "Each fluid ounce contains: * * * Vitamin B_1 25 mg. * * * Vitamin B_{12} (crystalline) 10 mcg." was false and misleading as applied to an article which contained less than the declared amounts of vitamins B_1 and B_{12}.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 10, 1952. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3692. Misbranding of Champion Compound. U. S. v. Cel-Ton-Sa Medicine Co. and Marvin Guyer. Pleas of guilty. Fine of $200 against each defendant. (F. D. C. No. 32744. Sample No. 31116–L.)

INFORMATION FILED: March 5, 1952, Southern District of Ohio, against the Cel-Ton-Sa Medicine Co., a partnership, Cincinnati, Ohio, and Marvin Guyer, a partner in the partnership.

ALLEGED SHIPMENT: On or about June 19, 1951, from the State of Ohio into the State of Tennessee.

LABEL, IN PART: (Bottle) "Champion Compound Contents 16 Fluid Ounces Active Laxative Ingredients: Buckthorn, Cascara Sagrada, Senna and Aloe. Active Carminative Ingredients: Ginger, Calamus, Anise, Fennel and Coriander. Inactive Ingredients: Gentian, Quassia, Burdock, Licorice, Mandrake, Salicylic Acid, Benzoic Acid, Iron and Ammonium Citrate, Saccharin Soluble, Oil Spearmint, Oil Cassia, Methyl Salicylate, Wahoo, Butternut, Sarsaparilla, Colocynth, Buchu, Uva Ursi, Juniper Berries, Wild Cherry, Caramel and Water $300 Prepared For ———— Address All Orders To Champion Remedies 118 Popular Ave., Memphis, Tenn."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Leading The Way To Improved Internal Hygiene" were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for general digestive disorders, minor stomach disorders, rheumatism, dropsical [*sic*], kidney and bladder ailments of a minor nature, incipient catarrh of the bladder, and gravel; that the article was a blood conditioner; that it contained therapeutically significant amounts of vitamins and minerals; and that it was effective in maintaining and restoring the health of the user. The article was not an adequate and effective treatment for the conditions stated and implied; it was not a blood conditioner; it did not contain therapeutically significant amounts of vitamins and minerals; and it would not be effective in maintaining and restoring the health of the user.

DISPOSITION: March 14, 1952. Pleas of guilty having been entered, the court imposed a fine of $200 against each defendant.

3693. Misbranding of Ceride solution and Kamide aqueous suspension. U. S. v. 1,975 Ampuls of Ceride solution, etc. (F. D. C. No. 30868. Sample Nos. 93124–K to 93127–K, incl.)

LIBEL FILED: March 23, 1951, Western District of North Carolina.

ALLEGED SHIPMENT: On or about February 13 and April 23, 1950, from Decatur, Ill., and New York, N. Y.

PRODUCT: 21,950 ampuls of *Ceride solution* and 23,950 ampuls of *Kamide aqueous suspension* at Andrews, N. C., in possession of Swan's Enterprises, Inc., and a number of 1-page leaflets entitled "Ceride and Kamide" and a number of 2-page leaflets entitled "Suggestions for the use of Ceride and Kamide."

RESULTS OF INVESTIGATION: The leaflets accompanying the products had been prepared locally for the consignee, Swan's Enterprises, Inc.

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*See also Nos. 3689–3691.

LABEL, IN PART: Portion of *Ceride solution.* (Ampul) "Ceride * * * 2 cc. Sterile Ampule Each cc. contains: Elemental Iodine, .00173 gm.; Cerium Iodide (CeI_3), .004125 gm.; Dextrose, .00767 gm. In distilled water" and (carton) "For intravenous Use."

Remainder of *Ceride solution.* (Ampul) "2 cc. Size Ceride" and (carton) "Ceride * * * Each cc. contains: Elemental Iodine 0.00158 Gm. Cerium Iodide 0.00457 Gm. Dextrose 0.0075 Gm. In distilled water * * * For Intravenous use."

Portion of *Kamide aqueous suspension.* (Ampul) "Kamide * * * 2 cc. Sterile Ampule Each cc. contains: Elemental Iodine, 0.00091 gm.; Potassium Iodide 0.00184 gm.; Starch, 0.0142 gm. In distilled water. Dose 2 cc. intramuscularly."

Remainder of *Kamide aqueous suspension* (Ampul) "2 cc. Kamide" and (carton) "Kamide * * * Each cc. contains: Elemental Iodine 0.001 Gm. Potassium Iodide 0.002 Gm. Starch 0.015 Gm. In distilled water * * * For Intramusular use."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling, namely, in the leaflets entitled "Ceride and Kamide" and "Suggestions for the use of Ceride and Kamide," were false and misleading. These statements represented and suggested that the *Ceride solution* was an adequate and effective treatment for arthritis, virus infections, toxemias of pregnancy, hay fever, asthma, hypertension, Buerger's disease, Raynaud's disease, coronary thrombosis, diabetes, encephalitis, herpes zoster, primary glaucoma, cerebral embolism, paralysis due to cerebral hemorrhage, menopause, malaria, poliomyelitis, gastric ulcer, phlebitis, rheumatic fever, and sinus infection; and that the *Kamide aqueous suspension* was an adequate and effective treatment for diseases of the nervous system and circulatory system, infections of the mucous membrane, arthritis, coronary thrombosis, edema of the brain, herpes zoster and other virus infections, hypertension, paralysis due to cerebral hemorrhage, cerebral embolism, poliomyelitis, rheumatic fever, and sinus infection. The articles were not adequate and effective treatments for such diseases and conditions.

The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 1, 1952. Swan's Enterprises, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond, conditioned that they be relabeled under the supervision of a representative of the Federal Security Administrator.

3694. Misbranding of A–T gum. U. S. v. 17 Cartons * * *. (F. D. C. No. 32496. Sample No. 4655–L.)

LIBEL FILED: February 8, 1952, Northern District of West Virginia.

ALLEGED SHIPMENT: On or about November 7, 1951, by Day-Baldwin, Inc., from Newark, N. J.

PRODUCT: 17 cartons, each containing 12 boxes and each box containing 14 tablets, of *A–T gum* at Clarksburg, W. Va.

LABEL, IN PART: (Box) "14 Tablets A–T Gum Antibiotic–Analgesic Each tablet contains aspirin 3½ grains and Tyrothricin 1 mg."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, namely, the box label and the display card entitled "Better Than Penicillin" which was shipped with the article, contained statements which were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for sore throat and minor throat and mouth infections, and that it was better than penicillin. The article was not an adequate and effective treatment for sore throat and minor throat and mouth infections, and it was not better than penicillin.

DISPOSITION: March 10, 1952. Default decree of condemnation and destruction.

3695. Misbranding of multivitamin capsules. U. S. v. 10,000 Capsules, etc. (F. D. C. No. 32509. Sample No. 32967–L.)

LIBEL FILED: February 13, 1952, Northern District of Illinois.

ALLEGED SHIPMENT: On or about January 11, 1952, from Detroit, Mich.

PRODUCT: 10,000 capsules in bulk and 73 bottles, each bottle containing 100 capsules, of *multivitamin capsules* in possession of Dr. Tark's Vitamins, Oak Park, Ill.

RESULTS OF INVESTIGATION: The article had been shipped in bulk, and the portion in the bottles had been repacked from the bulk shipment and relabeled by the consignee. A number of circulars entitled "With Thread Alone, You Cannot Sew," which had been printed locally, were in possession of Dr. Tark's Vitamins, the consignee.

LABEL, IN PART: (Bottle) "Dr. Tark's Vitamins One Capsule Daily Provides Vitamin A (Fish Liver Oil 5000 units, Vitamin D Irradiated Ergosterol) 1000 units, Vitamin B–1 (Thiamin Chloride) 2.5 mg., Vitamin B–2 (Riboflavin) 2.5 mg., Vitamin B–6 (Pyridoxine Hydrochloride) 0.5 mg., Vitamin C (Ascorbic Acid) 40. mg., Niacinamide 20. mg., Calcium Pantothenate 5. mg. Vitamin E (d-alpha tocopherol acetate) 2. I. U., Folic Acid 0.5 mg., Vitamin B–12 USP 1. mcg."

NATURE OF CHARGE: Misbranding, Section 502 (a), the above-referenced circular accompanying the article contained statements which were false and misleading. These statements represented and suggested that the article was effective in the prevention and treatment of neuritis, arthritis, rheumatism, caries of teeth, pyorrhea, common colds, listlessness, sleeplessness, nervousness, goiter, high blood pressure, heart disease, anemia, and hardening of the arteries, and that the article would help the blood stream remove calcium salts from the body, thereby relieving or preventing inflammatory rheumatism, stiff joints, and body aches and pains. The article was not effective in the prevention and treatment of the conditions stated and implied, and it was not capable of fulfilling the promises of benefit made for it. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 10, 1952. Default decree of condemnation. The court ordered that the product be delivered to a public institution, for the consumption of the inmates, but not for sale.

3696. Misbranding of Gum–Tone. U. S. v. 26 Cartons * * *. (F. D. C. No. 32343. Sample No. 35270–L.)

LIBEL FILED: January 3, 1952, District of North Dakota.

ALLEGED SHIPMENT: On or about September 12, 1951, from Hastings, Nebr., by Gum-Tone, Inc.

PRODUCT: 26 cartons, each containing 12 bottles, of *Gum-Tone* at Fargo, N. Dak. Analysis showed that the product was a powder containing sodium perborate 18.9%, soda, salt, calcium carbonate, and riboflavin.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Gum-Tone * * * Treatment for pyorrhea, gingivitis, bleeding gums, sore gums Massage gums and teeth twice daily for healthy oral conditions" were false and misleading since the article would not fulfill such promises of benefit.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: February 28, 1952. The owner of the product having agreed to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3697. Misbranding of Color-Therm device. U. S. v. 1 Device * * *. (F. D. C. No. 32458. Sample No. 55196–K.)

LIBEL FIELD: February 13, 1952, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about October 14, 1948, by Fred Gerkey, from Mission, Kans.

PRODUCT: *1 Color-Therm device* at Oklahoma City, Okla. The device consisted of tubes for producing colored lights similar to neon lights, together with electrical connections needed for operating them.

LABEL, IN PART: "Color Therm Dr. Fred Gerkey Mission, Kansas."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements appearing in the instruction sheet shipped with the device were false and misleading since they represented and suggested that the device was effective in the treatment of any disease condition and, in particular, disorders of the liver and eyes, female trouble, sinus trouble, asthma, and nervousness, whereas it was not effective for such purposes.

DISPOSITION: April 2, 1952. Default decree of condemnation. The court ordered that the device be delivered to the Food and Drug Administration for exhibit and educational purposes.

3698. Misbranding of Howard Cabinet devices. U. S. v. 2 Devices, etc. (F. D. C. No. 29401. Sample No. 81190–K.)

LIBEL FILED: July 14, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 24, 1950, by Mr. O's Products, from Huntington Park, Calif.

PRODUCT: 2 *Howard Cabinet devices* and 100 circulars entitled "The Howard Original Cabinet" at Bala-Cynwyd, Pa.

The device consisted of a masonite and plywood box or cabinet, which was closed with curtains equipped with a zipper. Holes in the curtains permitted the head and arms to remain outside the cabinet. The cabinet contained a chair, an electric heating unit, a blower, a pan to hold water, and a timing device.

LABEL, IN PART: "The Howard Original Cabinet Model 1700 FL."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned circulars which accompanied the devices were false and misleading. The statements represented and suggested that the device would

make one feel younger, relax nerves, relieve tired feeling, help faulty complexion, improve circulation, help relieve pains, reduce weight, relieve heavy colds, aid in breaking up certain types of internal congestion, aid liver and kidneys, help overcome effects of excessive drinking, relieve some types of headaches, induce sleep, aid women in keeping their figures, complexion, and health, help keep off excessive weight, make one feel better, help women during menstrual periods and while going through the change, aid in tapering down swollen legs and bulging hips, aid in treating arthritis and rheumatism, improve general health, rid the body of impurities through perspiration, relieve aching muscles and joints, restore vitality, and relax overwrought nerves of the nervous and physically exhausted. The device was not effective for the purposes stated and implied.

DISPOSITION: December 20, 1950. The Healthomatic Corp., Bala-Cynwyd, Pa., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3699. Misbranding of Alkatone. U. S. v. 15 Bottles, etc. (F. D. C. No. 32491. Sample Nos. 35411–L, 35412–L.)

LIBEL FILED: February 4, 1952, Southern District of Iowa.

ALLEGED SHIPMENT: On or about November 6 and 13, 1951, by the Peerless Serum Co., Kansas City, Mo.

PRODUCT: 15 1-pound bottles and 22 5-pound cans of *Alkatone* at Des Moines, Iowa, and a price list entitled "Peerless June 15, 1950 Price List."

LABEL, IN PART: (Bottle and can) "Alkatone (With Nicotinic Acid) Poison * * * Contains: Sodium Hydroxide 10%, Nicotinic Acid, Copper Sulphate, Sodium Thiosulphate, Methylene Blue, Sodium Bicarbonate, Salt, Oil Anise."

NATURE OF CHARGE: Misbranding, Section 502 (a), the designation "Alkatone" on the label and the following statements appearing in the price list accompanying the article were false and misleading: "Alkatone (With Nicotinic Acid). Nicotinic acid has been found to be a beneficial factor in the treatment of the majority of outbreaks of necrotic enteritis, including the so-called 'Bloody Diarrhea' type, and aids in the control of these conditions." The designation and statements represented and suggested that the article was an alkalizing tonic and was effective in the treatment of necrotic enteritis and bloody diarrhea in animals, whereas it was not an alkalizing tonic and would not be effective for the purposes so represented.

DISPOSITION: April 1, 1952. Default decree of condemnation and destruction.

3700. Misbranding of Rex Hunters Dog Powders. U. S. v. 73 Cartons * * *. (F. D. C. No. 31313. Sample No. 24880–L.)

LIBEL FILED: July 3, 1951, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about August 30 and November 8, 1950, by J. Hilgers & Co., from Binghamton, N. Y.

PRODUCT: 73 cartons of *Rex Hunters Dog Powders* at Harrisburg, Pa.

LABEL, IN PART: "Rex Hunters Dog Powders Contains: Arsenic Trioxide 1/50 grain, Phenolphthalein, Iron and Ammonium Citrate, Potassium Iodide, Calcium Phosphate, Precipitated Sulphur * * * Contents: 40 Powders in tablet form."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the carton label of the article and in the folder entitled "Directions Read Carefully Man's Best Friend—The DOG!" enclosed in the carton were false and misleading. The statements represented and suggested that the article was effective in the treatment of dogs affected with disease conditions characterized by excessive scratching, itching, loose coat, listlessness, bad breath, poor appetite, and simple skin irritations; that regular use of the article was effective in keeping dogs in top physical condition; that the article was a tonic, reconstructive, and regulator; and that its use with other of the products distributed by J. Hilgers & Co. was effective to help prevent the occurrence of running or barking fits in dogs. The article was not effective for such purposes, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: January 17, 1952. Default decree of condemnation and destruction.

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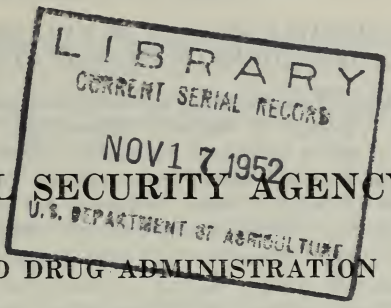
PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1952



FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3701–3720

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *September 24, 1952.*

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3701. Misbranding of amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Robert M. Walker (Closson-Kelly Drugs), and James Mason. Plea of guilty by Robert M. Walker. Sentence of 6 months in jail on each of 3 counts, to run concurrently. Plea of not guilty by James Mason. Tried to a jury. Verdict of not guilty. (F. D. C. No. 31284. Sample Nos. 29849–L to 29852–L, incl., 29976–L to 29979–L, incl.)

INFORMATION FILED: November 28, 1951, Western District of Washington, against Robert M. Walker, trading as Closson-Kelly Drugs, at Seattle, Wash., and James Mason, an employee of Closson-Kelly Drugs.

INTERSTATE SHIPMENT: Prior to the sales described below, various quantities of *amphetamine sulfate tablets* were shipped into the State of Washington, from New York, N. Y., and various quantities of *Seconal Sodium capsules* were shipped into the State of Washington, from Indianapolis, Ind.

ALLEGED VIOLATION: On March 29 and 30 and April 2, 3, and 5, 1951, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *amphetamine sulfate tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: On March 26, 1952, James Mason having entered a plea of not guilty to each of the 6 counts in which he was charged, he was tried to a jury, which returned a verdict of not guilty.

On April 10, 1952, Robert M. Walker changed his plea from not guilty to guilty on each of 3 counts of the information, and he was sentenced to 6 months in prison on each of these counts, the sentences to run concurrently. The remaining counts of the information against Robert M. Walker were dismissed on motion of the Government.

3702. Misbranding of dextro-amphetamine sulfate tablets, pentobarbital sodium capsules, and Seconal Sodium capsules. U. S. v. Georgia Drug Store, Inc., and Willie W. Gross, Sr. Pleas of nolo contendere. Georgia Drug Store, Inc., fined $250. Willie W. Gross, Sr., placed on probation for two years, conditioned that he serve three months in jail if corporation failed to pay fine. (F. D. C. No. 31297. Sample Nos. 777–L, 1313–L, 1315–L, 1316–L, 1511–L, 1512–L.)

INFORMATION FILED: February 12, 1952, against Georgia Drug Store, Inc., Atlanta, Ga., and Willie W. Gross, Sr., president of the corporation.

INTERSTATE SHIPMENT: Within the period from on or about September 22, 1950, to on or about April 5, 1951, various quantities of *dextro-amphetamine sulfate tablets*, *pentobarbital sodium capsules*, and *Seconal Sodium capsules* were shipped in interstate commerce from the States of Pennsylvania, Illinois, and Indiana, into the State of Georgia.

ALLEGED VIOLATION: On April 23, 26, 27, and 28, and May 1 and 2, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* and the *Seconal Sodium capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug.

DISPOSITION: February 29, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $250 against the corporation and placed Willie W. Gross, Sr., on probation for 2 years, conditioned that if the fine levied on the corporation were not paid, he would serve 3 months in jail.

3703. Misbranding of amphetamine sulfate tablets and dextro-amphetamine sulfate tablets. U. S. v. Fred G. Hansard (H & Y Drug), and Arvil Cravens. Fred G. Hansard pleaded nolo contendere and fined $100 on count 1, $500 on count 2, and placed on probation for 2 years on remaining 3 counts. Arvil Cravens pleaded guilty and sentenced to 5 days in jail and $100 fine on count 2 and placed on probation for 2 years. (F. D. C. No. 31269. Sample Nos. 13660–L to 13664–L, incl.)

INFORMATION FILED: December 5, 1951, Northern District of Texas, against Fred G. Hansard, trading as the H & Y Drug, at Amarillo, Tex., and Arvil Cravens, pharmacist.

INTERSTATE SHIPMENT: On or about November 13 and 14, 1950, and February 5, 1951, from Philadelphia, Pa., and Wichita, Kans., of quantities of *amphetamine sulfate tablets* and *dextro-amphetamine sulfate tablets*.

ALLEGED VIOLATION: On February 2, 3, 4, and 6, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the drugs being misbranded.

Fred G. Hansard was charged with the violations involved in each of the 5 counts of the information, and Arvil Cravens was joined as a defendant in counts 2 and 5 and was charged with the violations involved in those counts.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the

manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear any directions for use.

DISPOSITION: February 8, 1952. Fred G. Hansard having entered a plea of nolo contendere, he was found guilty and was fined $100 on count 1 and $500 on count 2. Sentence was suspended, however, on the remaining 3 counts, and he was placed on probation for 2 years.

Arvil Cravens having entered a plea of guilty, he was sentenced to 5 days in jail and was fined $100 on count 2. Sentence against this defendant was suspended on count 5, and he was placed on probation for 2 years.

3704. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Ben Ratliff (Ratliff Drug Store), and Charles Abercrombie. Pleas of guilty. Ben Ratliff fined $400 and Charles Abercrombie fined $100. Both defendants placed on probation for 2 years. (F. D. C. No. 31281. Sample Nos. 13368–L to 13372–L, incl.)

INFORMATION FILED: December 5, 1951, Northern District of Texas, against Ben Ratliff, trading as Ratliff Drug Store, at Amarillo, Tex., and Charles Abercrombie, pharmacist.

INTERSTATE SHIPMENT: Prior to the dates of the sales described below, various quantities of *dextro-amphetamine sulfate tablets* were shipped from Philadelphia, Pa., into the State of Texas.

ALLEGED VIOLATION: On February 3, 4, and 6, 1951, while the drug was being held for sale after shipment in interstate commerce, various quantities of the drug were repackaged and dispensed without a physician's prescription, which acts resulted in the drug being misbranded.

Ben Ratliff, as owner of the store, was charged with the violations involved in all counts of the information, and Charles Abercrombie was joined as a defendant in the 2 counts in which the sales were made by him.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; Section 502 (f) (1), the repackaged drug failed to bear directions for use; and, Section 502 (e) (1), the repackaged drug in one sale failed to bear a label containing the common or usual name of the drug.

DISPOSITION: February 9, 1952. Pleas of guilty having been entered, the court fined Ben Ratliff $100 on each of 4 counts of the information, suspended imposition of sentence on count 5, and placed him on probation for 2 years.

Charles Abercrombie was fined $100 on one of the counts on which he was charged; imposition of sentence was suspended on the second count; and he was placed on probation for 2 years.

3705. Misbranding of dextro-amphetamine sulfate tablets and Amytal tablets. U. S. v. Widder's Pharmacy, Inc., and Abraham Kass and Jacob Kass. Pleas of guilty. Corporation fined $150, Abraham Kass fined $150, and Jacob Kass fined $150, together with costs. (F. D. C. No. 32748. Sample Nos. 9633–L to 9638–L, incl.)

INFORMATION FILED: March 24, 1952, against Widder's Pharmacy, Inc., Chicago, Ill., and Abraham Kass, secretary-treasurer, and Jacob Kass, president of the corporation.

INTERSTATE SHIPMENT: Prior to the dates of the sales set forth below, various quantities of *dextro-amphetamine sulfate tablets* and *Amytal tablets* were shipped in interstate commerce into the State of Illinois.

ALLEGED VIOLATION: On March 14, 15, and 27, and April 4, 5, and 17, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repackaged and sold without a physician's prescription, which acts resulted in the drugs being misbranded.

The Widder's Pharmacy, Inc., was charged with causing the acts of repacking and sale of the drugs involved in each of the 6 counts of the information; and, in addition, Abraham Kass was charged with the violations involved in 3 counts and Jacob Kass was charged with the violations involved in the remaining counts of the information.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *Amytal tablets* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged tablets bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (2), the repackaged *dextro-amphetamine sulfate tablets* failed to bear a label containing the common or usual name of each active ingredient of the drug.

DISPOSITION: April 22, 1952. Pleas of guilty having been entered, the court fined the corporation $25 on each of the 6 counts of the information, and fined both Abraham Kass and Jacob Kass $50 on each of the 3 counts in which they were named as defendants, a total fine of $450, together with costs.

3706. Misbranding of amphetamine phosphate tablets and pentobarbital sodium capsules. U. S. v. Julius H. Wendt (Mutual Drug Store). Plea of nolo contendere. Sentence of 6 months in jail on count 1 and 6 months on each of remaining counts, to run concurrently with sentence on count 1. (F. D. C. No. 31270. Sample Nos. 15993–L, 15996–L to 16000–L, incl.)

INFORMATION FILED: December 11, 1951, Northern District of Oklahoma, against Julius H. Wendt, trading as the Mutual Drug Store, Tulsa, Okla.

INTERSTATE SHIPMENT: On or about September 15, 1950, from St. Louis, Mo., into the State of Oklahoma, of quantities of *amphetamine phosphate tablets* and *pentobarbital sodium* capsules.

ALLEGED VIOLATION: On February 8, 21, and 22, 1951, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and sold without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *amphetamine phosphate tablets* failed to bear a label containing the common or usual name of the drug.

DISPOSITION: February 13, 1952. A plea of nolo contendere having been entered the court sentenced the defendant to 6 months in jail on count 1 and 6 months on each of the remaining 5 counts, the sentences on counts 2 to 6, inclusive, to run consecutively with the sentence on count 1.

3707. Alleged misbranding of Seconal Sodium capsules, dextro-amphetamine sulfate tablets, and sulfadiazine tablets. U. S. v. Isom Drug Co., Walter S. Isom, Sr., and William N. Patillo. Pleas of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 30026. Sample Nos. 70830–K to 70832–K, incl., 70834–K, 70835–K, 70837–K.)

INFORMATION FILED: February 13, 1951, Western District of Oklahoma, against the Isom Drug Co., a partnership, Oklahoma City, Okla., and against Walter S. Isom, Sr., a partner in the partnership, and William N. Patillo, a pharmacist employed by the partnership.

ALLEGED SHIPMENT: From the States of Indiana and New York into the State of Oklahoma, of quantities of *Seconal Sodium capsules*, *dextro-amphetamine sulfate tablets*, and *sulfadiazine tablets*.

ALLEGED VIOLATION: On or about April 22, 24, 25, and 28, and May 1, 1950, while the drugs were being held for sale at the Isom Drug Co. after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The Isom Drug Co. and Walter S. Isom, Sr., were charged with causing the acts of relabeling and dispensing of the drugs involved in each of the 6 counts of the information; and, in addition, William N. Patillo was joined as a defendant in one of the counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *Seconal Sodium capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *sulfadiazine tablets* failed to bear warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: The defendants filed a motion for a bill of particulars and a motion to quash the information, and on September 27, 1951, the court overruled such motions. Thereafter, the case came on for trial before the court upon the defendants' pleas of not guilty. On January 23, 1952, at the conclusion of the trial, the court returned a verdict of not guilty.

3708. Misbranding of pentobarbital sodium capsules. U. S. v. Maurice Booke (Del-Mor Pharmacy). Plea of guilty. Fine, $1,000. (F. D. C. No. 31259. Sample No. 88896–K).

INFORMATION FILED: December 3, 1951, Western District of New York, against Maurice Booke, trading as Del-Mor Pharmacy, Buffalo, N. Y.

INTERSTATE SHIPMENT: Between the approximate dates of July 31 and October 4, 1950, from the State of Illinois into the State of New York, of a quantity of *pentobarbital sodium capsules.*

ALLEGED VIOLATION: On December 4, 1950, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a quantity of the drug to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: December 18, 1951. A plea of guilty having been entered, the court fined the defendant $1,000.

3709. Misbranding of Dexedrine Sulfate tablets. U. S. v. Joe C. Nace. Plea of guilty. Defendant placed on probation for 3 years. (F. D. C. No. 31098. Sample Nos. 2856–L, 2883–L, 2887–L.)

INFORMATION FILED: October 8, 1951, Southern District of West Virginia, against Joe C. Nace, manager of the McDowell Pharmacy, War, W. Va.

INTERSTATE SHIPMENT: From the State of Tennessee into the State of West Virginia, of quantities of *Dexedrine Sulfate tablets.*

ALLEGED VIOLATION: On or about January 23 and March 6 and 13, 1951, while the tablets were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged tablets failed to bear a label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged tablets failed to bear adequate directions for use.

DISPOSITION: January 15, 1952. A plea of guilty having been entered, the court placed the defendant on probation for 3 years.

3710. Misbranding of sulfadiazine tablets, Ergoapiol with savin capsules, and methyltestosterone linguets. U. S. v. Harmon S. Cover (Wiechelman Drugs), and Joseph Ralenkotter. Pleas of guilty. Harmon S. Cover fined $75 and Joseph Ralenkotter fined $25. (F. D. C. No. 32739. Sample Nos. 84690-K, 84929-K, 84957-K.)

INFORMATION FILED: February 28, 1952, Eastern District of Kentucky, against Harmon S. Cover, trading as Wiechelman Drugs at Covington, Ky., and Joseph Ralenkotter, a pharmacist for Wiechelman Drugs.

INTERSTATE SHIPMENT: Prior to the date of the sales referred to below, quantities of *sulfadiazine tablets*, *Ergoapiol with savin capsules*, and *methyltestosterone linguets* were shipped in interstate commerce into the State of Kentucky.

ALLEGED VIOLATION: On or about August 3, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of capsules of *Ergoapiol with savin* to be sold and dispensed to a purchaser in the original box in which the capsules had been shipped in interstate commerce, without the prescription of a physician; and on or about December 8 and 14, 1950, the defendants repacked various quantities of *sulfadiazine tablets* and *methyltestosterone linguets* and sold the repackaged drugs without prescriptions, which acts of the defendants resulted in the drugs being misbranded.

Harmon S. Cover was charged with causing the violations involved in all counts, and Joseph Ralenkotter was joined in one count of the information and charged with the violation involved in that count.

NATURE OF CHARGE: *Ergoapiol with savin capsules.* Misbranding, Section 502 (f) (1), the labeling of the drug bore no directions for use. (The box in which the capsules were shipped in interstate commerce bore no directions for use since it was exempted from such requirement by the statement on the label "Caution: To be dispensed only by or on the prescription of a physician." The act of the defendants in dispensing the drug without a physician's prescription caused the exemption to expire.)

Sulfadiazine tablets and *methyltestosterone linguets.* Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Sulfadiazine tablets. Misbranding, Section 502 (e) (1), the drug failed to bear a label containing the common or usual name of the drug; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: March 10, 1952. Pleas of guilty having been entered, the court fined Harmon S. Cover $75 and Joseph Ralenkotter $25.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3711. Adulteration of passion flower herb and gelsemium root. U. S. v. 32 Bales, etc. (F. D. C. No. 32854. Sample Nos. 12096-L, 12097-L.)

LIBEL FILED: March 7, 1952, Southern District of Indiana.

ALLEGED SHIPMENT: On or about September 29, 1949, and October 4, 1951, from Boone and Statesville, N. C.

PRODUCT: 32 300-pound bales of *passion flower herb* and 8 340-pound bales of *gelsemium root* at Tipton, Ind., in possession of the Inland Alkaloid Co.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances (the *passion flower herb* contained rodent excreta, rodent hairs, and insects, and the *gelsemium root* contained rodent hairs and insect fragments); and, Section 501 (a) (2), the *gelsemium root* had been held under insanitary conditions whereby it may have become contaminated with filth. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: June 2, 1952. The Inland Alkaloid Co. having consented to the destruction of the products, judgment of forfeiture was entered and the court ordered that the products be destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3712. Adulteration and misbranding of procaine penicillin G. U. S. v. 647 Vials, etc. (F. D. C. No. 31977. Sample Nos. 18292–L to 18294–L, incl.)

LIBEL FILED: November 7, 1951, District of Arizona.

ALLEGED SHIPMENT: On or about May 29, 1951, from San Francisco, Calif.

PRODUCT: *Procaine penicillin G.* 837 10-cc. vials, and 14 boxes, each containing 1-cc. cartridge, at Phoenix, Ariz.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements (837-vial lot) "10 cc. size * * * 3,000,000 units * * * Each cc contains 300,000 units" and (14-box lot) "1 cc. size (300,000 Units)" were false and misleading since the potency of the article was less than stated on the labels.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 21, 1952. Default decree of condemnation and destruction.

3713. Adulteration and misbranding of Liv-Vi-B. U. S. v. 24 Vials * * *. (F. D. C. No. 32874. Sample No. 39833–L.)

LIBEL FILED: March 12, 1952, Southern District of California.

ALLEGED SHIPMENT: On or about April 9, June 30, and December 13, 1948, from Passaic, N. J.

PRODUCT: 24 10-cc. vials of *Liv-Vi-B* at Los Angeles, Calif. Analysis showed that the product contained approximately 59 percent of the declared amount of thiamine hydrochloride.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Each 1 cc. contains * * * not less than 10 mgms. (3330 units) thiamine hydrochloride" was false and misleading as applied to the article, which contained less than 10 milligrams (3,330 units) of thiamine hydrochloride.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 7, 1952. Default decree of condemnation and destruction.

3714. **Adulteration and misbranding of Uni-Swabs. U. S. v. 360 Packages * * *.** (F. D. C. 32866. Sample No. 10497–L.)

LIBEL FILED: March 12, 1952, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about January 24, 1952, by Steri-Swabs, Inc., from Hollis, Long Island, N. Y.

PRODUCT: 360 packages of *Uni-Swabs* at Detroit, Mich. The product consisted of pledgets of absorbent cotton on sticks.

LABEL, IN PART: (Package) "200 Individual Uni-Swabs, Sterile When Packed."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the label declared that the article was sterile when packed, whereas it was not sterile when packed but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterile When Packed" was false and misleading.

DISPOSITION: April 4, 1952. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3715. **Misbranding of Diaplex. U. S. v. 2 Cases * * *.** (F. D. C. No. 31706. Sample Nos. 13633–L, 13634–L.)

LIBEL FILED: On or about September 21, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 27, 1951, by John McVey, identified as H. W. Pierce, from Carr, Colo.

PRODUCT: 2 cases, each containing 25 cartons, of *Diaplex* at Clarksdale, Mo. Examination indicated that the product was a species of saltbush, such as *Atriplex canescens.*

LABEL, IN PART: (Some cartons) "Diaplex for Diabetics * * * for further information address % H. W. Pierce, Wellington, Colo., U. S. A. * * * Net Weight 12 ounces avoirdupois"; (other cartons) "Diaplex Directions (For a delicious beverage * * *."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on some of the carton labels were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for diabetes, and that use of the article by diabetics would render treatment with insulin unnecessary. The article was worthless in the treatment of diabetes.

Further misbranding, Section 502 (e) (1), the label of the article failed to bear the common or usual name of the drug.

DISPOSITION: On or about October 19, 1951. Default decree of condemnation and destruction.

3716. **Misbranding of Diaplex. U. S. v. 5 Cartons * * *.** (F. D. C. No. 32219. Sample No. 21142–L.)

LIBEL FILED: On or about December 18, 1951, Northern District of Texas.

*See also Nos. 3712–3714.

ALLEGED SHIPMENT: On or about September 12, 1951, by Mrs. H. W. Pierce, from Carr, Colo.

PRODUCT: 5 cartons, each containing 12 ounces, of *Diaplex* at San Angelo, Tex. Samples taken from other shipments of *Diaplex* were found to consist of a species of saltbush, such as *Atriplex canescens.*

LABEL, IN PART: (Carton) "Diaplex for Diabetics * * * for further information address c/o H. W. Pierce, Wellington, Colo."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements borne on the carton label were false and misleading: "Diaplex for Diabetics * * * A diabetic should drink * * * Diaplex * * * watch the urine test daily and you will be amazed at the results. * * * Persons using Diaplex with insulin should make the urine test daily, and as the pancreas increases its normal functions, reduce the amount of insulin sufficiently to avoid insulin reaction. Only use enough insulin to take care of the surplus sugar, and eventually eliminate the insulin entirely. But continue the use of Diaplex until you are well and strong. Persons who have never used insulin, and not in coma, will find it unnecessary to do so. All that will be required is to adhere to a good diabetic diet and drink two quarts of Diaplex for a few months, and like thousands of others he, too, will rejoice in the grand activity of good health and vigor." These statements represented and suggested that the article was an adequate and effective treatment for diabetes, and that its use would render unnecessary the use by diabetics of insulin, whereas the article was not an adequate and effective treatment for diabetes, and its use would not render unnecessary the use by diabetics of insulin.

DISPOSITION: April 21, 1952. Default decree of condemnation and destruction.

3717. Misbranding of liver extract. U. S. v. 169 Packages * * *. (F. D. C. No. 32430. Sample No. 26648–L.)

LIBEL FILED: January 14, 1952, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 9 and December 3, 1951, by the Lederle Laboratories, Division American Cyanamid Co., from Pearl River, N. Y.

PRODUCT: 169 packages, each containing 3 1–cc. vials, of *liver extract* at Philadelphia, Pa.

Examination disclosed that the product contained approximately 10 micrograms of vitamin B_{12} per cubic centimeter.

LABEL, IN PART: (Package) "Concentrated Solution Liver Extract * * * Each cc contains 20 Microgm of Vitamin B_{12} by Biological Assay."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Each cc contains 20 Microgm of Vitamin B_{12}" borne on the label was false and misleading since the product contained less than that amount of vitamin B_{12}.

DISPOSITION: April 22, 1952. Default decree of condemnation and destruction.

3718. Misbranding of vitamin tablets. U. S. v. 864 Packages, etc. (F. D. C. No. 31202. Sample No. 25305–L.)

LIBEL FILED: June 18, 1951, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: During April 1945, by Major Vitamins, Inc., from New York, N. Y.

PRODUCT: 864 24-tablet packages, 1,008 48-tablet packages, and 1,008 cartons, each carton containing 1 100-tablet bottle, of *vitamin tablets* at Conshohocken, Pa.

LABEL, IN PART: "Major B Complex Brand Natural Vitamin Tablets * * * [or "Major-B Brand Natural Vitamin B Complex with added thiamine Tablets"]."

	Each Tablet		*(3 Tablets)*
	Milligrams	*Micrograms*	*Micrograms*
Thiamine (Vitamin B_1)	.333	333	1,000
Riboflavin (Vitamin B_2)	0.166	166	500
Pyridoxine (Vitamin B_6)	0.026	26	80
Pantothenic Acid	0.083	83	250
Niacin	0.166	166	500

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article in the packages and cartons, namely, in a leaflet entitled "Buoyant Health For All The Family," which was enclosed in each package and carton, were false and misleading. The statements represented and suggested that the article was effective to provide greater energy, steadier nerves, better digestion, improved health and vigor, better appetite, insurance from vitamin deficiencies, and physical well-being, and protection against frequent colds, constipation, fatigue, digestive upsets, and other common ills; that the article would provide the vitamins found in whole wheat bread, eggs, milk, liver, and tomato juice; that there are widespread dietary deficiencies that would be corrected by use of the article; that the article contained nutritionally significant amounts of all vitamins of the B-complex; that foods are an unreliable source of vitamins for the reasons specified; and, therefore, that it was desirable, if not necessary, to supplement the ordinary diet with the article. The article was not capable of fulfilling the promises of benefit made for it, and the statements were contrary to fact.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 29, 1951. Default decree of condemnation and destruction.

3719. Misbranding of Rexair device. U. S. v. 94 Devices, etc. (F. D. C. No. 27277. Sample No. 41923–K.)

LIBEL FILED: June 27, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about April 1, 1949, by the Rexair Div., Martin-Parry Corp., from Toledo, Ohio.

PRODUCT: 94 *Rexair devices* and 10 copies of booklets entitled "Rexair The Modern Home Appliance" and "King of The Air" at Chicago, Ill.

LABEL, IN PART: "Rexair Conditioner and Humidifier."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the above-mentioned booklets, which accompanied the devices, were false and misleading. The statements represented and suggested that the device, through removal of dust from the air, was effective to hasten convalescence and prevent asthma, hay fever, and tuberculosis; and that the device was effective in preventing air-borne infections, causing 85% of deaths from infectious diseases, including pneumonia, tuberculosis, diphtheria, bronchitis, colds, influenza, la grippe, asthma, catarrh, croup, hay fever, sinus infections, tonsillitis, measles, scarlet fever, meningitis, typhoid, tetanus, septic sore throat, allergic diarrhea, and infantile eczema. The device was not capable of fulfilling the claims of benefit stated and implied.

DISPOSITION: January 21, 1952. The Martin-Parry Corp., claimant, having filed an answer denying that the devices under seizure were misbranded and the Government and the claimant having subsequently agreed to the entry of an order, the court entered its order stating that the devices under seizure were, when shipped, in contravention of Section 502 (a), and directing that such devices, with the consent of the claimant, be delivered by the United States marshal to some public or charitable hospital within the Northern District of Illinois, under labeling to read as follows:

"The Rexair machine is a portable electric cleaner that retains the material collected in a reservoir of water, thus affording a means of disposing of the collected material without shaking it into the air or otherwise handling it.

"The Rexair machine is unique in that its cleaning and dust retaining properties are sufficiently complete to make it useful as an adjunct in the home and hospital to afford symptomatic relief in a protected area or atmosphere such as a closed room for some sufferers of house dust allergy and pollen allergy.

"In addition to its other properties, the Rexair machine, when used according to directions, is capable of increasing the moisture content of dry air."

The court order also directed that the labeling that accompanied the devices shipped in 1949 should be disposed of by the United States marshal in accordance with Section 304 (d).

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR A LABEL CONTAINING AN ACCURATE STATEMENT OF THE QUANTITY OF THE CONTENTS*

3720. Misbranding of epsom salt, isopropyl alcohol rubbing compound, and mineral oil. U. S. v. Roisman Products Co. Plea of nolo contendere. Fine of $50 and probation for 3 years. (F. D. C. No. 31303. Sample Nos. 16171–L, 16174–L, 31962–L, 31963–L.)

INFORMATION FILED: February 11, 1952, Western District of Oklahoma, against the Roisman Products Co., a partnership, Oklahoma City, Okla.

ALLEGED SHIPMENT: Between the approximate dates of July 18, 1950, and February 5, 1951, from the State of Oklahoma into the States of Kansas and Missouri.

LABEL, IN PART: (Carton) "Fulvalu Epsom Salts * * * Contains ½ lb. when Packed"; (bottle) "Roico Isopropyl Alcohol Rubbing Compound * * * Contents 1 Pint Roisman Products Co"; (bottle) "Stephens' Isopropyl Alcohol Rubbing Compound * * * One Fluid Pint Distributed By Stephens Products Co"; (bottle) "Stephens' Heavy Mineral Oil * * * 1 Fl. Pint Packed For Stephens Products Co. * * * Oklahoma City, Okla."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the packages and bottles failed to bear labels containing accurate statements of the quantity of the contents since they contained less than the declared amounts.

The information charged also (in count 1) the interstate shipment of a quantity of imitation vanilla flavor which was misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

*See also Nos. 3701–3710.

DISPOSITION: February 15, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $25 on each of the first 2 counts of the information, suspended the imposition of sentence on the remaining 3 counts, and placed the defendant on probation for a period of 3 years.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3701 TO 3720

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3701, 3707) Prosecution contested.

[1] (3701, 3707) Prosecution contested.

U. S. GOVERNMENT PRINTING OFFICE: 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3721–3740

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *October 29, 1952.*

CONTENTS*

*For presence of a habit-forming narcotic without warning statement, see Nos. 3726–3729; omission of, or unsatisfactory, ingredients statements, Nos. 3721, 3725, 3728–3730; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3721, 3723–3730; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3721, 3723, 3725, 3726, 3728–3730.

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NEW DRUGS SHIPPED WITHOUT EFFECTIVE APPLICATION

3721. Misbranding of cortisone acetate tablets. U. S. v. Edward Strauss. Plea of nolo contendere. Fine of $500 and sentence of one year in prison; prison sentence suspended and defendant placed on probation for one year. (F. D. C. No. 31279. Sample Nos. 25354–L, 25355–L.)

INFORMATION FILED: January 2, 1952, District of New Jersey, against Edward Strauss, manager of Strauss Pharmacy, Elizabeth, N. J.

ALLEGED SHIPMENT: On or about March 2 and 5, 1951, from the State of New Jersey into the State of New York.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; Section 502 (e) (1), the article failed to bear a label containing the common or usual name of the drug; and, Sections 502 (f) (1) and (2), the labeling of the article failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: April 25, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $500 and a sentence of one year in prison. The court suspended the prison sentence and placed the defendant on probation for one year.

3722. Misbranding of Histamist. U. S. v. 7 Display Cartons * * *. (F. D. C. No. 32436. Sample No. 35436–L.)

LIBEL FILED: January 14, 1952, Southern District of Iowa.

ALLEGED SHIPMENT: On or about March 28, 1951, by the Histamist Corp., from Chicago, Ill.

PRODUCT: 7 display cartons, each containing 12 1¾-ounce bottles, of *Histamist* at Ottumwa, Iowa. Analysis disclosed that the article was a solution containing methapyrilene hydrochloride and desoxyephedrine hydrochloride.

LABEL, IN PART: (Bottle) "Histamist An Antihistaminic and Decongestant nasal solution."

NATURE OF CHARGE: Section 505 (a), the article was a drug which may not be introduced or delivered for introduction into interstate commerce since it was a new drug and an application filed pursuant to Section 505 (b) was not effective with respect to the drug.

Misbranding, Section 502 (a), the following statements appearing on the display carton were false and misleading since the article was not an effective treatment for the conditions referred to: "Histamist * * * for Head Colds — Sinus Misery * * * Helps resist infection * * * Check constant sore throats, infections, etc. from sinus drip Use Histamist for Direct Relief * * * Do you have splitting sinus headaches? Smokers catarrh? Use Histamist for prompt relief * * * Do you have head colds, sinusitis * * * sinus headaches? Use Histamist Check head cold and sinus misery in minutes Direct nasal sprays, for Direct relief."

DISPOSITION: March 10, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3723. Misbranding of dextro-amphetamine sulfate tablets, methamphetamine hydrochloride tablets, and diethylstilbestrol tablets. U. S. v. Frank Schwilk (Schwilk's Pharmacy). Plea of nolo contendere. Fine, $300. (F. D. C. No. 31283. Sample Nos. 84692–K, 10862–L, 11057–L, 11663–L, 11953–L.)

INFORMATION FILED: On or about January 21, 1952, Southern District of Ohio, against Frank Schwilk, trading as Schwilk's Pharmacy, at Dayton, Ohio.

INTERSTATE SHIPMENT: From the States of Pennsylvania, Illinois, and Indiana, into the State of Ohio, of quantities of *dextro-amphetamine sulfate tablets*, *methamphetamine hydrochloride tablets*, and *diethylstilbestrol tablets*.

ALLEGED VIOLATION: On or about December 18, 1950, and January 5 and 16 and February 7 and 8, 1951, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), a portion of the *dextro-amphetamine sulfate tablets* and a portion of the repackaged *methamphetamine hydrochloride tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (f) (2), all of the *methamphetamine hydrochloride tablets* failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 24, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $300.

3724. Misbranding of sulfadiazine tablets, thyroid tablets, conjugated estrogen tablets, and dextro-amphetamine sulfate tablets. U. S. v. Central Drug Co., Oscar W. Howser, and Allen T. Howser. Pleas of guilty. Central Drug Co. fined $200, Oscar W. Howser fined $100, and Allen T. Howser fined $50. (F. D. C. No. 32702. Sample Nos. 72175–K, 11292–L, 11626–L, 11646–L.)

INFORMATION FILED: April 2, 1952, Southern District of Ohio, against the Central Drug Co., a corporation, Steubenville, Ohio, Oscar W. Howser, pharmacist and president of the corporation, and Allen T. Howser, pharmacist and secretary-treasurer of the corporation.

INTERSTATE SHIPMENT: Prior to the dates of the sales, various quantities of *sulfadiazine tablets*, *thyroid tablets*, *conjugated estrogen tablets*, and *dextro-amphetamine sulfate tablets* were shipped in interstate commerce into the State of Ohio.

ALLEGED VIOLATION: On January 12, 1950, and May 3, 23, and 24, 1951, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were caused to be repacked and sold without a physician's prescription.

*See also No. 3721.

The Central Drug Co. was named as a defendant in all counts of the information, and, in addition, Oscar W. Howser was joined as a defendant in two of the counts and Allen T. Howser was joined as a defendant in one of the counts and charged with the violations involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (f) (2), the labeling of the *sulfadiazine tablets* failed to bear adequate warnings against use of the drug in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: April 8, 1952. Pleas of guilty having been entered, the court imposed a fine of $200 against the corporation, $100 against Oscar W. Howser, and $50 against Allen T. Howser.

3725. Misbranding of Combisul-TD tablets, thyroid tablets, and sulfathiazole tablets. U. S. v. Irvin J. Kalt (Kalts Drugs). Plea of nolo contendere. Fine, $300. (F. D. C. No. 30621. Sample Nos. 84934–K, 85057–K, 85058–K.)

INFORMATION FILED: November 26, 1951, Southern District of Ohio, against Irvin J. Kalt, trading as Kalts Drugs, Dayton, Ohio.

ALLEGED SHIPMENT: On or about August 11 and December 12, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (2), the labels of the repackaged drugs failed to bear adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

Further misbranding, Section 502 (b) (1), the repackaged *sulfathiazole tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (2), the repackaged *Combisul-TD tablets* failed to bear a labed containing the common or usual name of each active ingredient of the tablets; and, Section 502 (f) (1), the labeling of the repackaged *Combisul-TD tablets* and *thyroid tablets* failed to bear adequate directions for use.

DISPOSITION: April 24, 1952. A plea of nolo contendere having been entered, the court imposed a fine of $300.

3726. Misbranding of pentobarbital sodium capsules. U. S. v. Red Star Pharmacy, Inc. (J. F. Epstein Drugs), and Jerome F. Epstein. Pleas of guilty. Fine of $100 against individual and $1 against corporation. (F. D. C. No. 31299. Sample No. 4851–L.)

INFORMATION FILED: April 3, 1952, District of Massachusetts, against Red Star Pharmacy, Inc., trading as J. F. Epstein Drugs, Boston, Mass., and Jerome F. Epstein, president-treasurer of the corporation.

INTERSTATE SHIPMENT: From the State of New York into the State of Massachusetts, of a quantity of *pentobarbital sodium capsules.*

ALLEGED VIOLATION: On or about July 5, 1951, while the drug was being held for sale after shipment in interstate commerce, the defendants caused a number of capsules of the drug to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: June 24, 1952. Pleas of guilty having been entered, the court imposed a fine of $100 against the individual and a fine of $1 against the corporation.

3727. Misbranding of pentobarbital sodium capsules. U. S. v. Fred J. Kwako (Kwako Drugs). Plea of guilty. Fine, $100. (F. D. C. No. 31292. Sample Nos. 76000–K, 91442–K, 91445–K, 19212–L, 19224–L.)

INFORMATION FILED: December 19, 1951, District of Minnesota, against Fred J. Kwako, trading as Kwako Drugs, at Pelican Rapids, Minn.

INTERSTATE SHIPMENT: From the State of Illinois into the State of Minnesota, of a number of *pentobarbital sodium capsules.*

ALLEGED VIOLATION: On or about November 27 and December 6 and 20, 1950, and January 9 and February 15, 1951, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of capsules to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: May 5, 1952. A plea of guilty having been entered, the court imposed a fine of $100.

3728. Misbranding of Seconal Sodium capsules and methyltestosterone tablets. U. S. v. John Homer Harrison and Joel Reibstein. Pleas of guilty. Fine of $100 against John Homer Harrison and $75 against Joel Reibstein, together with costs. (F. D. C. No. 31288. Sample Nos. 70432–K, 70512–K, 70513–K, 70702–K, 70703–K, 89785–K, 90016–K.)

INFORMATION FILED: January 28, 1952, District of Kansas, against John Homer Harrison and Joel Reibstein, pharmacists and comanagers of the Jayhawk Drug Store, Topeka, Kans.

INTERSTATE SHIPMENT: On or about August 31 and October 10 and 23, 1950, from the States of New Jersey and Missouri into the State of Kansas, of quantities of *Seconal Sodium capsules* and *methyltestosterone tablets*.

ALLEGED VIOLATION: On November 6, 9, 14, 20, and 29, 1950, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a physician's prescription, which acts resulted in the drugs being misbranded.

John Homer Harrison was charged with making the sales involved in 4 of the counts, and Joel Reibstein was charged with making the sales involved in the remaining 3 counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the label of the repackaged *methyltestosterone tablets* failed to bear the common or usual name of the drug; and, Section 502 (b) (1), a portion of the repackaged *methyltestosterone tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: February 11, 1952. Pleas of guilty having been entered, the court imposed a fine of $100 against John Homer Harrison and a fine of $75 against Joel Reibstein, together with costs.

3729. Misbranding of Tuinal capsules and Benzedrine Sulfate tablets. U. S. v. Grover Stanton and Joseph F. Ernst (Gus B. Grover & Co.). Pleas of nolo contendere. Fine of $50 against each defendant. (F. D. C. No. 29438. Sample Nos. 51935–K, 51936–K, 54004–K, 54031–K, 54032–K.)

INDICTMENT RETURNED: January 4, 1951, Southern District of Mississippi, against Grover Stanton and Joseph F. Ernst, copartners in a partnership trading as Gus B. Grover & Co., Natchez, Miss.

ALLEGED VIOLATION: On or about June 20 and August 12, 1949, the defendants caused a number of *Tuinal capsules* and *Benzedrine Sulfate tablets* which were misbranded to be introduced and delivered for introduction into interstate commerce, at Natchez, Miss., for delivery into the State of Ohio.

On or about September 28, 1949, while a number of the *Tuinal capsules* and *Benzedrine Sulfate tablets* were being held for sale at the store of Gus B. Grover & Co., Natchez, Miss., after shipment in interstate commerce, the de-

fendants caused a quantity of these tablets and capsules to be repacked and disposed of without a physician's prescription, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the repackaged drugs bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *Tuinal capsules* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and their labels failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (b) (1), the label of a portion of the *Benzedrine Sulfate tablets* failed to bear the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (e) (1), all lots of the *Benzedrine Sulfate tablets* failed to bear labels containing the common or usual name of the tablets.

DISPOSITION: November 20, 1951. Pleas of nolo contendere having been entered, the court imposed a fine of $50 against each defendant.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3730. Adulteration and misbranding of sulfathiazole and Sulmet. U. S. v. 4 Drums, etc. (F. D. C. No. 32044. Sample Nos. 30418-L, 30419-L.)

LIBEL FILED: November 23, 1951, District of Oregon.

ALLEGED SHIPMENT: On or about July 6, 1951, from New York, N. Y.

PRODUCT: 4 30-pound drums of *sulfathiazole* and 196 1-gallon jars of *Sulmet* at Portland, Oreg.

RESULTS OF INVESTIGATION: Investigation revealed that the products had been immersed in flood waters and that the labels had been obliterated.

NATURE OF CHARGE: Adulteration, Section 501 (a) (2), the articles had been held under insanitary conditions whereby they may have become contaminated with filth.

Misbranding, Sections 502 (b) (1) and (2), the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (e) (1), the labels of the articles failed to bear the common or usual name of the drugs.

DISPOSITION: February 11, 1952. Default decree of condemnation and destruction.

3731. Adulteration of psyllium husks (Plantago). U. S. v. 33 Bags * * *. (F. D. C. No. 32229. Sample No. 37199-L.)

LIBEL FILED: December 13, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about February 13, 1951, from India.

PRODUCT: 33 200-pound bags of *psyllium husks* (Plantago) at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance by reason of the presence of insects. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 18, 1952. The Esscolloid Co., Inc., Minneapolis, Minn., claimant, having consented to the entry of a decree, judgment or condemnation was entered and the court ordered that the product be released under bond for the salvaging of the fit portion, under the supervision of the Food and Drug Administration. 6,302 pounds were salvaged.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3732. Adulteration of phenobarbital tablets. U. S. v. 13 Bottles * * *. (F. D. C. No. 32512. Sample No. 38451–L.)

LIBEL FILED: February 11, 1952, District of New Jersey.

ALLEGED SHIPMENT: On or about January 8, 1952, by Bonded Laboratories, Inc., from Brooklyn, N. Y.

PRODUCT: 13 bottles each containing 1,000 *phenobarbital tablets* at East Orange, N. J.

LABEL, IN PART: (Bottle) "1000 Pulvoids No. 462 Phenobarbital 1½ grains."

NATURE OF CHARGE: Adulteration, Section 501 (b), the strength of the article differed from, and its quality fell below, the standard established for *phenobarbital tablets* since the tablets contained less than 94 percent of the labeled amount of phenobarbital, the minimum permitted by the United States Pharmacopeia, and since they failed to meet the test for "Disintegration" specified in that compendium.

DISPOSITION: March 26, 1952. Default decree of condemnation and destruction.

3733. Adulteration of adhesive bandages. U. S. v. 21 Boxes * * *. (F. D. C. No. 32308. Sample No. 10456–L.)

LIBEL FILED: January 10, 1952, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about November 8, 1951, by Gotham Aseptic Laboratory Co., Inc., from Long Island City, N. Y.

PRODUCT: *Adhesive bandages.* 21 boxes, each containing 36 envelopes containing the article at Bay City, Mich.

LABEL, IN PART: (Envelope) "Skin-Tone Plain Gauze Pads Gotham Waterproof Six Sterile Bands Stickrite Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Adhesive Absorbent Bandage," the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the standard set forth in that compendium since it was not sterile as provided therein, but was contaminated with viable microorganisms.

DISPOSITION: March 28, 1952. Default decree of condemnation and destruction.

3734. Adulteration of rubber prophylactics. U. S. v. 175 Gross * * *. (F. D. C. No. 32369. Sample No. 13913–L.)

LIBEL FILED: January 2, 1952, District of Colorado.

ALLEGED SHIPMENT: A portion of the article was shipped by the Allied Latex Corp., from East Newark, N. J., on or about September 26, 1950, and the remainder was transported by Dixie Laboratories, a subisidiary of the Gibson Products Co., from Seagoville, Tex., on or about July 30, 1951.

PRODUCT: 175 gross of *rubber prophylactics* at Denver, Colo. Examination of 108 devices showed that 6, or 5.5%, were defective in that they contained holes.

LABEL, IN PART: (Carton) "Smithies Prophylactics * * * manufactured by The Allied Latex Corp., East Newark, New Jersey."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess. The article was adulterated when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: March 19, 1952. The Allied Latex Corp. having executed an acceptance of service and an authorization for taking of a final decree, the court entered a decree of condemnation and destruction.

3735. Adulteration and misbranding of clinical thermometers. U. S. v. 205 Devices * * *. (F. D. C. No. 31963. Sample No. 26756–L.)

LIBEL FILED: November 7, 1951, Northern District of California.

ALLEGED SHIPMENT: On or about June 6, 1951, by the Dittmar Thermometer Co., from Hollis, N. Y.

PRODUCT: 205 *clinical thermometers* at San Francisco, Calif. Examination of 24 thermometers showed that 2 failed to meet the hard shaker test and 4 failed to give accurate readings. Five of the 24 were tested for pigment retention, and all five failed to meet this test.

LABEL, IN PART: (12-unit box) "Timico Clinical Thermometer Style Rectal."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements appearing on the envelopes containing the thermometers were false and misleading since the article failed to meet the tests specified in Commercial Standard CS1–32, U. S. Department of Commerce, for hard shaker, pigment retention, and accurate readings: "This certifies that the thermometer bearing the above identification number has been tested and compared with standards verified by U. S. Government Bureau of Standards and found correct at this date within tolerances specified for accuracy in Commercial Standard CS1–32 U. S. Department of Commerce. This thermometer is guaranteed to be of absolute accuracy."

DISPOSITION: March 20, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3736. Action to enjoin and restrain the interstate shipment of misbranded mineral tablets, B complex vitamins with iron tablets, and Mo Tee Na tablets. U. S. v. Nature's Mineral Food Co., Perry B. Smith, and Thornton B. Smith. Permanent injunction granted. (Inj. No. 234.)

COMPLAINT FILED: October 19, 1951, Southern District of Indiana, against the Nature's Mineral Food Co., a partnership, Indianapolis, Ind., and Perry B. Smith and Thornton B. Smith, partners in the partnership, alleging that the defendants had been introducing and delivering, and were continuing to introduce and deliver, for introduction into interstate commerce, *mineral tablets, B complex vitamins with iron tablets,* and *Mo Tee Na tablets* which were misbranded.

*See also Nos. 3722, 3735.

LABEL, IN PART: "The M. F. Co.'s Minerals 270 Tablets * * * Contains: Potassium Iodide, Calcium Phosphate, Calcium Carbonate, Sodium Phosphate, Iron Sulfate Exsiccated, Sodium Chloride (Iodized salt)"; "55 B Complex Vitamins With Iron * * * Contains Vitamin B_1, 1 mg. (thiamin chloride) Vitamin B_2, 0.5 mg. (riboflavin) Niacin, 5 mg. Sodium Iron Pyrophosphate, 0.4 gr. Yeast plus inert compounding ingredients"; and "Mo Tee Na * * * Net contents 100 Tablets * * * Active Ingredients: Calcium Succinate and Aspirin."

NATURE OF CHARGE: *Mineral tablets* and *B complex vitamins with iron tablets.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of the articles, namely, in leaflets entitled "The M. F. Co.'s Vitamin B Complex" and "Mineral Supplement"; mimeographed sheets entitled "Nature's Minerals Vitamins," "Cochrane on the Ball," "Important," and "Dr. William Brady Says"; a mimeographed letter addressed "Good Morning Dear Friend"; and a card entitled "Supplement Your Mineral and Vitamin Diet," were false and misleading.

The statements represented and suggested that the articles would supply a universal need, and that they would be effective in reducing illness and increasing efficiency; in treating lack of resistance, loss of weight, congestion of blood, and weakness of muscles; in effecting normal nerve functioning, lactation, and reproduction and digestive actions; in preventing weakness of the legs, flabbiness of the heart muscles, and lowering of the body temperature; in maintaining health and strength; in fortifying the body against inroads of sickness; in antagonizing the aging process; in preventing a run-down condition; in correcting unnatural basic disorders that cause illness or disease regardless of their names; in making over physical wrecks, causing them to be happy, strong, free from stubborn suffering, pain and soreness of long duration, and able to sleep; in preventing the return of agonizing pain; in treating nervousness, stomach seeming to be tied up in a knot, insomnia, inability to work, and irritability; in treating patients helpless with rheumatism, suffering with indigestion and stomach trouble, or run-down generally; and in treating chronic rheumatism, hay fever, hives, sick headache, "nervous" headache, allergy, crumbling teeth, excessive tooth decay, recurring or chronic spinal curvature, growing pains, adult tetany (cramps in legs or arms at night), recurring chilblains, and watery "drip-drip" from the nose, with fits of sneezing which many Yankee wiseacres ascribe to imaginary sinusitis and which they think sounds better than "catarrh." The articles would not be effective for such purposes and conditions, and would not fulfill the promises of benefit stated and implied.

Mo Tee Na tablets. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, namely, on the card entitled "Supplement Your Mineral and Vitamin Diet," were false and misleading. The statements represented and suggested that the article was adequate and effective in the cure, mitigation, and treatment of aches and pains of all types, misery, arthritis, and neuritis, and that it would enable one to enjoy life in the daytime and sleep well at night. The article was not adequate and effective in the cure, mitigation, and treatment of the conditions stated and implied.

The *mineral tablets* and the *B complex vitamins with iron tablets* were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 21, 1951. The defendants having consented to the entry of a decree, the court issued a permanent injunction, perpetually enjoining the defendants from the acts complained of.

3737. Misbranding of Trokells tablets. U. S. v. 109 Display Cartons * * *. (F. D. C. No. 29850. Sample No. 69431–K.)

LIBEL FILED: October 26, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about July 20, 1950, by Humphreys Medicine Co., Inc., from New York, N. Y.

PRODUCT: 109 display cartons, each containing 12 packages, of *Trokells tablets*, at Pittsburgh, Pa. Included in each package was a leaflet entitled "Trokells".

LABEL, IN PART: (Package and bottle) "Trokells Antibiotic-Analgesic Tablets * * * Active Ingredients: Tyrothricin, 2 Mg. Benzocaine, 5 Mg. * * * 12 tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not an effective treatment for the conditions stated and implied and was not effective against disease-producing germs generally: (On display carton) "For Prevention and Relief of common throat & mouth irritations * * * Acts as fast or faster than penicillin on bacteria that cause common sore throat * * * New Miracle Germ Killer"; (on 12-tablet carton) "For the relief of common throat & mouth irritations * * * useful in helping to prevent and relieve common throat and mouth irritation"; (on 12-tablet bottle) "For the relief of common throat & mouth irritations"; and (on leaflet entitled "Trokells") "For the relief of throat irritations * * * germ-killing Tyrothricin * * * raw sore throat and hoarseness resulting from colds."

DISPOSITION: May 15, 1952. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

3738. Misbranding of Blake's Mineral Compound. U. S. v. 80 Packages * * *. (F. D. C. No. 31617. Sample No. 13490–L.)

LIBEL FILED: August 14, 1951, District of Utah.

ALLEGED SHIPMENT: On or about December 10, 1950, and July 12, 1951, by the Hy-Life Mineral Co., from Denver, Colo.

PRODUCT: 80 packages, each containing 3½ pounds, of *Blake's Mineral Compound* at Salt Lake City, Utah.

LABEL, IN PART: (Package) "Blake's Mineral Compound * * * Ingredients: (active) Ammonium Chloride; Potassium Chlorate; Sodium Sulphate; Calcium Carbonate; Tobacco Powder."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements borne on the label were false and misleading since they represented and suggested that the article was effective in the prevention and treatment of bloat in sheep and cattle, whereas it was not effective for such purposes: "A chemical preparation which, when mixed with salt as directed, is designed for feeding sheep and cattle while pasturing in green Alfafa, Clover, or in Corn and Wheat Fields. * * * 1. Mix entire contents of this package (3½ lbs.) with 100 lbs. of finely ground salt. * * * Remove All Other Salt From Your Livestock. Place this mixture in troughs conveniently accessible to livestock. Note: Feed above mixture to livestock for several days before turning them into green pastures and constantly thereafter."

Further misbranding, Section 502 (a), the name "Blake's Mineral Compound" and the above-quoted directions on the label, together with the follow-

ing statements from the label, were false and misleading: "2. When grain is fed—for example, to dairy cows—mix one 3½-lb. package of Blake's Mineral Compound with Only 15 Lbs. of Finely Ground Salt. Use this mixture to season the grain. Allow from one to two level tablespoons per head for cattle, or two level teaspoons per head for sheep. In addition to treating the grain ration when one is fed, be certain also to have the mixture described in paragraph one (above) available in troughs." The name of the article, the directions, and the representations on the label represented and suggested that the article furnished essential minerals required by sheep and cattle. However, ammonium chloride and sodium sulfate, two of the declared active ingredients, are not required by sheep and cattle; tobacco powder is not a mineral; and, when used as directed, the article furnished inconsequential nutritional amounts of potassium chlorate and calcium carbonate.

DISPOSITION: On September 28, 1951, pursuant to stipulation between the United States attorney and counsel for the claimant, the Hy-Life Mineral Co., an order was entered in the District Court for the District of Utah, removing the case for trial to the District of Colorado. On November 28, 1951, the United States attorney for the District of Colorado filed a petition to remand the case to the District of Utah. This petition was granted by order of March 12, 1952. On April 11, 1952, no claim or other pleading having been filed in the District of Utah, default was noted and the court ordered the product condemned and destroyed.

3739. Misbranding of Guysol. U. S. v. 7 Bottles * * *. (F. D. C. No. 32482. Sample No. 39797–L.)

LIBEL FILED: February 5, 1952, Southern District of California.

ALLEGED SHIPMENT: On or about November 7, 1951, by the Peerless Serum Co., from Kansas City, Mo.

PRODUCT: 7 bottles of *Guysol* at Riverside, Calif.

LABEL, IN PART: (Bottle) "Peerless 1 gallon Guysol Each ounce Contains Creosote, Guaiacol Liquid, Oil Eucalyptus, Cresylic Acid, Gum Camphor, Emulsifying Base."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, namely, in a leaflet entitled "Peerless Serum Company Seasons Fall and Winter" and in a booklet entitled "Peerless June 15, 1950 Price List," were false and misleading. The statements represented and suggested that the article was effective in the treatment of infections and disorders of the respiratory tract of animals, including poultry, and in the treatment of forage poisoning in horses and cattle, whereas the article was not effective in the treatment of such conditions.

DISPOSITION: February 29, 1952. Default decree of condemnation and destruction.

3740. Misbranding of Pocco Powder and Baby Chick Starter. U. S. v. 20 Packages, etc. (F. D. C. No. 32545. Sample Nos. 35291–L, 35293–L.)

LIBEL FILED: February 27, 1952, District of Minnesota.

ALLEGED SHIPMENT: Between the approximate dates of February 28, 1950, and September 21, 1951, by the C. U. McClellan Laboratories Corp., from Los Angeles, Calif.

PRODUCT: 20 1-pound packages and 6 5¼-pound packages of *Pocco Powder*, and 4 cases, each containing 24 100-tablet bottles, 7 cases, each containing 12 500-tablet bottles, and 1 case, containing 12 1,000-tablet bottles, of *Baby Chick Starter* at Worthington, Minn., together with a number of booklets entitled "1951 Price List."

LABEL, IN PART: (Package) "McClellan's Pocco Powder * * * Contains the following ingredients—Iron Sulphate, Sulphur, Gentian, Cream of Tartar, Salt Peter, Quassia, Potassium Iodide, Calcium Sulphide, Charcoal"; (Bottle) "McClellan's Baby Chick Starter Tabs * * * Contains Potassium Permanganate, Potassium Dichromate, Ferrous Sulfate, Montmorillonite * * * 15-grain tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles and in the accompanying booklets were false and misleading. The statements represented and suggested that the *Pocco Powder* was an alterative for poultry and that the *Baby Chick Starter* would act as an astringent and mild antiseptic for the mucous membrane of the intestinal tract in noncontagious diarrhea. These statements were contrary to fact.

DISPOSITION: April 10, 1952. Default decree of destruction.

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PRODUCTS

[1] (3736) Injunction issued.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3736) Injunction issued.

U. S. GOVERNMENT PRINTING OFFICE: 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3741–3760

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *November 12, 1952.*

CONTENTS*

*For presence of a habit-forming narcotic without warning statement, see Nos. 3743–3746; omission of, or unsatisfactory, ingredients statements, No. 3746; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3743, 3745, 3746; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3744, 3745; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3757.

226781—52——1

DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

3741. Misbranding of RecTone devices. U. S. v. 9 Cartons, etc. (F. D. C. No. 32156. Sample No. 16377–L.)

LIBEL FILED: November 29, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about June 6 and October 4 and 16, 1951, by the Walker-Young Corp., from Long Beach, Calif.

PRODUCT: *RecTone devices.* 9 cartons, each carton containing 1 rubber bulb air pump with hose and 10 RecTone medicators, with some of the cartons containing a leaflet printed in blue ink and other cartons containing a leaflet printed in black ink, both entitled "RecTone The Method of Humane Rectal Therapy," and one carton containing a leaflet entitled "Reference Manual," at Kansas City, Mo. In addition to the 9 cartons, there were 3 cartons, each containing 10 RecTone medicators and one of the leaflets entitled "RecTone * * *" in blue or black ink, also at Kansas City, Mo.

Each RecTone medicator was inclosed in a cellophane envelope and consisted of a cylindrical, elastic, finger-like bag closed at one end and having an open tube at the other for attaching to the air pump. The medicators were approximately 5 inches long and between ½ inch and ¾ inch in maximum diameter.

LABEL, IN PART: (Cellophane envelope) "RecTone Medicator The Medicament Herein Contains: Benzocain 4% Phenol 0.5% Boric Acid, Bismuth Subnitrate, Resorcin 0.5% Balsam Peru, Zinc Oxide and Aquaphor Water Soluble Base."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used as suggested in its labeling, namely, by inserting into the rectum and inflating.

Further misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the above-mentioned leaflets, were false and misleading. The statements represented and suggested that the article was an effective treatment for piles; for restoring rectal health and a sense of well-being to the individual; for hemorrhoids; for bleeding, itching, or burning conditions of the anal canal; for stricture of the anal canal; for destroying infection and reviving fresh blood circulation in the strangulated hemorrhoidal vein system, thus enabling the natural healing powers of the blood to operate in releasing nerve tension and mending ailing tissue; for chronic conditions of the anal tract; for retoning rectal nerves and muscles; for enabling the all-important sphincter muscles to become pliable and strong and resume their normal function; and for controlling scar tissue and speeding up the healing process following surgery. The article was not an effective treatment for such conditions, and it was not capable of fulfilling the promises of benefit made for it.

DISPOSITION: January 22, 1952. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3742. Hormone feed. U. S. v. 11 Bags, etc. (F. D. C. No. 30807. Sample Nos. 29453–L, 29454–L.)

LIBEL FILED: February 26, 1951, Western District of Washington.

ALLEGED SHIPMENT: On or about September 2, 1950, by Wessanan's Koninklijke Fabrieken, N. V., from Wormerveir, Holland.

PRODUCT: 11 bags, each containing 4 packages, and 1 bag, containing 2 packages, together with 3 additional packages, of *hormone feed* at Nisqually, Wash.

RESULTS OF INVESTIGATION: There was in the possession of the consignee a letter from the shipper dated June 2, 1950, representing the article as effective to promote growth and improve meat and fat of cattle, chickens, and other farm animals.

LABEL, IN PART: (Package) "10 K. G. Vevoron 95 Majsmel 5 Veveron—Methyl-thiouracil"; (shipping case) "Vevoron for Cattle."

NATURE OF CHARGE: Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: July 1, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3743. Misbranding of dextro-amphetamine sulfate tablets and Seconal Sodium capsules. U. S. v. Hoffman's Pharmacy and Guy W. Hoffman. Pleas of nolo contendere. Each defendant fined $150 and placed on probation for 1 year. (F. D. C. No. 32710. Sample Nos. 1549–L, 1551–L, 1880–L, 1881–L, 1885–L, 1886–L.)

INFORMATION FILED: May 2, 1952, Northern District of Georgia, against Hoffman's Pharmacy, a partnership, Atlanta, Ga., and Guy W. Hoffman, a partner in the partnership.

ALLEGED VIOLATION: On or about August 22 and September 4 and 5, 1951, while a number of *dextro-amphetamine sulfate tablets* and *Seconal Sodium capsules* were being held for sale at Hoffman's Pharmacy after shipment in interstate commerce, the defendants caused quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

*See also No. 3760 (veterinary preparations).

DISPOSITION: June 5, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $150 against each of the defendants and placed them on probation for 1 year.

3744. Misbranding of Seconal Sodium capsules. U. S. v. Calvin H. Garner. Plea of guilty. Fine, $250. (F. D. C. No. 31282. Sample Nos. 13198–L, 13199–L.)

INFORMATION FILED: December 5, 1951, Northern District of Texas, against Calvin H. Garner, a pharmacist, employed at the Earl Burns Drugs store, Sweetwater, Tex.

INTERSTATE SHIPMENT: From the State of Indiana into the State of Texas, of quantities of *Seconal Sodium capsules.*

ALLEGED VIOLATION: On or about April 27 and May 2, 1951, while the drug was being held for sale after shipment in interstate commerce, the defendant caused quantities of the drug to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of a portion of the repackaged drug was false and misleading since it represented and suggested that the repackaged drug was "Dilantin Sodium," manufactured by Parke, Davis & Co., whereas the drug was *Seconal Sodium*, manufactured by Eli Lilly & Co.; and the labeling of the remainder of the repackaged drug was false and misleading since it represented and suggested that the drug was "High Blend B Complex With Liver and Vitamin C," whereas the drug was *Seconal Sodium.*

Further misbranding, Section 502 (b) (1), the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (d), the repackaged drug contained *Seconal Sodium*, a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged drug failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: May 2, 1952. A plea of guilty having been entered, the court imposed a fine of $250.

3745. Misbranding of phenobarbital tablets and pentobarbital sodium capsules. U. S. v. Joseph P. Cataldo (Winton Pharmacy), and Derwent William McCann. Pleas of guilty. Fine of $500 against Defendant Cataldo and $250 against Defendant McCann. (F. D. C. No. 32743. Sample Nos. 6760–L, 6767–L, 6769–L, 7762–L, 7763–L.)

INFORMATION FILED: March 31, 1952, Western District of New York, against Joseph P. Cataldo, trading as the Winton Pharmacy, Rochester, N. Y., and Derwent William McCann, a pharmacist employed by Joseph P. Cataldo.

ALLEGED VIOLATION: On or about February 12 and March 12, 1951, while a number of the *phenobarbital tablets* and *pentobarbital sodium capsules* were being held for sale at the Winton Pharmacy after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing accurate statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drugs contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (1), the repackaged *phenobarbital tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: May 26, 1952. Pleas of guilty having been entered, the court imposed a fine of $500 on each of the 2 counts of the information against Defendant Cataldo and a fine of $250 on each of the 2 counts against Defendant McCann, after which the court suspended the fines which had been imposed against the defendants on count 2 of the information.

3746. Misbranding of Donnatal tablets and sulfadiazine tablets. U. S. v. Dewberry Drug Co., Ltd., Milton Temerson, Walker N. Fricks, Grafton G. Smith, and James O. Self. Pleas of nolo contendere. Fine of $50 against each defendant. (F. D. C. No. 31287. Sample Nos. 75113–K, 752–L, 21403–L, 21424–L to 21426–L, incl.)

INFORMATION FILED: December 19, 1951, Northern District of Alabama, against Dewberry Drug Co., Ltd., a partnership, Birmingham, Ala., and against Milton Temerson, a partner in the partnership, and Walker N. Fricks, Grafton G. Smith, and James O. Self, pharmacists for the partnership.

INTERSTATE SHIPMENT: From the States of Virginia and Missouri into the State of Alabama, of quantities of *Donnatal tablets* and *sulfadiazine tablets*.

ALLEGED VIOLATION: On or about September 7, 1950, and January 17, March 8, and May 5 and 7, 1951, while the drugs were being held for sale after shipment in interstate commerce, various quantities of the drugs were repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

The partnership and Milton Temerson were charged with causing the acts of repacking and dispensing of the drugs involved in each of the 6 counts of the information. In addition, Walker N. Fricks in 1 count, Grafton G. Smith in 1 of the other counts, and James O. Self in 1 of the 2 other counts were charged with causing the acts involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (b) (2), the repackaged *sulfadiazine tablets* failed to bear a label containing an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Donnatal tablets* contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged *Donnatal tablets* failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (e) (2), the repackaged *Donnatal tablets* were fabricated from two or more ingredients, and the label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, as are necessary for the protection of users.

DISPOSITION: January 10, 1952. Pleas of nolo contendere having been entered, the court imposed a fine of $50 against each of the defendants.

3747. Misbranding of Vitoplus capsules, vitamin A capsules, vitamin B complex capsules, and d-alpha-tocopheryl acetate capsules. U. S. v. 115 Bottles, etc. (F. D. C. No. 32022. Sample Nos. 9902–L, 9903–L, 9905–L to 9907–L, incl.)

LIBEL FILED: November 23, 1951, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 21, September 21, and October 5, 1951, from Detroit, Mich., by the Gelatin Products Div., R. P. Scherer Corp.

PRODUCT: 115 100-capsule bottles of *Vitoplus capsules*, 1 15,000-capsule box and 49 50-capsule bottles of *vitamin A capsules*, 156 100-capsule bottles of *vitamin B complex capsules*, and 139 100-capsule bottles of *d-alpha-tocopheryl acetate capsules* at Chicago, Ill., together with a number of booklets entitled "Healthway Products Almanac 1951."

RESULTS OF INVESTIGATION: All of the products originally were shipped in bulk, and those products contained in the bottles represented the portions of the products which had been repackaged by the consignee, the Illinois Herb Co., Chicago, Ill. The booklets which are referred to above were printed locally and were to be sent by mail to prospective customers.

LABEL, IN PART: (Bottle) "100 Vitoplus No 59 Capsules Ingredients in each capsule: Liver Desiccated – 200 mg. Ferrous Sulfate, Dried USP – 136.1 Mg. (Equivalent to 40 mg. of iron) Thiamin Hydrochloride USP – 1 mg. Riboflavin USP – 2 mg. A fermentation extract equivalent in microbiological potency to Vitamin B_{12} – 1 microgram."

(Box) "Quantity 15,000 * * * Ingredients in each capsule * * * Vitamin A 25,000 USP Units."

(Bottle) "50 Soluble Gelatin Vitamin A Capsules Each Capsule Contains: 25,000 USP Units (Fish Liver Oil)."

(Bottle) "No. 190 100 Capsules Healthway Therapeutic Type B Complex Ingredients in each capsule: Thiamin Hydrochloride USP (Vitamin B_1) 5 mg. Riboflavin USP (Vitamin B_2) 5 mg. Pyridoxine Hydrochloride (Vitamin B_6) 1 mg. Calcium Pantothenate 25 mg. Niacin Amide USP 50 mg. With other B-Complex factors from liver."

(Bottle) "100 No. 709 Vim-EE Capsules Each capsule contains d-alpha Tocopheryl Acetate (from vegetable oils) equivalent by biological assay to 50 International Units Vitamin E."

NATURE OF CHARGE: *Vitoplus capsules.* Misbranding, Section 502 (a), the following statements and design appearing in the accompanying booklet were misleading since the article was not effective for the purposes stated and implied: (Page 15) "Get this 'Red Magic' for Your Blood Building Program [picture of a bottle labeled "Vitoplus Capsules Vitamin B_{12}"] * * * feel full of zest and able to enjoy life to it's fullest measure. If you feel 'all done in' or 'washed out' most of the time, if your days seem to drag along because of that wornout feeling * * * blood that is deficient in red blood cells * * *." Further misbranding, Section 502 (a), the following statements and design in the accompanying booklet were misleading since the need for vitamin B_{12} in human nutrition has not been established, and any useful properties of it other than in pernicious anemia have not been recognized: (Page 15) "Dynamic Vitamin B_{12} * * * [picture of a bottle labeled "Vitoplus Capsules Vitamin B_{12}"] the other vitamins do their work quicker and more efficiently * * * dynamic Red Magic Vitamin B_{12}, in the quantity necessary to aid your blood-building program * * *." Further misbranding, Section 502 (a), the statement on the bottle label "Ingredients in each capsule Liver Desiccated – 200 mg. * * *" was misleading since the label of the article failed to reveal the material fact that the amount of dried liver supplied by the article when taken as directed was essentially inconsequential.

Vitamin A capsules. Misbranding, Section 502 (a), the following statements in the booklet accompanying the article were false and misleading since the article was not effective for the purposes stated and implied: (Page 26) "Sinusitis–Head Colds–Catarrh? * * * sinus distress * * * dry skin * * * Lack of energy * * * impairment of teeth and bones * * * Vitamin A Capsules * * *."

Vitamin B complex capsules. Misbranding, Section 502 (a), the following statements in the booklet accompanying the article were false and misleading since the article was not effective for the purposes stated and implied: (Page 26) "Diet for liver disorder * * * supplemented with Vitamin B Complex improved the health of patients with cirrhosis of the liver * * * B Complex group of Vitamins * * * spark the human machine in consuming and using the elements that supply the nerves and system with body building and sustaining fuel * * * No. 190 Vitamin B Complex Capsules * * *." Further misbranding, Section 502 (a), the statement appearing in the accompanying booklet, namely, (page 26) "Every person needs the B Complex Vitamins," was misleading in the absence of a statement of the material fact that the B complex vitamins are normally supplied by the diet. Further mis-

branding, Section 502 (a), the designation "Healthway" appearing on the bottle label was false and misleading since the use of the article would not assure maintenance or restoration of the user's health.

d-alpha-tocopheryl acetate capsules. Misbranding, Section 502 (a), the following statements in the booklet accompanying the article were false and misleading since the article was not effective for the purposes stated and implied: (Page 20) "Value in menopause (change of life) * * * treatment of heart disease * * * preserving tooth enamel * * * prevention of fatty livers * * * protect the body in keeping the Vitamin A reserve up to par * * * betterment in your health * * * No. 709 Vim-EE Capsules * * *."

The articles were alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce.

Vitamin A capsules. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in this respect when introduced into and while in interstate commerce.

The *d-alpha-tocopheryl acetate capsules* were alleged also to be misbranded when introduced into and while in interstate commerce, under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 1, 1952. Default decree of condemnation and destruction.

3748. Misbranding of Hope Mineral tablets. U. S. v. 32 Dozen Bottles, etc. (and 26 other seizure actions). (F. D. C. Nos. 32995, 33008 to 33012, incl., 33014, 33015, 33017 to 33019, incl., 33023, 33032, 33037, 33038, 33043, 33045, 33046, 33163, 33171, 33172, 33176, 33178, 33179, 33185, 33186, 33203 to 33206, incl., 33253. Sample Nos. 2109–L, 2110–L, 3841–L to 3843–L, incl., 5095–L, 5097–L, 6446–L, 6447–L, 7317–L, 7318–L, 8731–L, 10197–L, 10198–L, 21925–L, 21927–L, 24915–L, 24921–L, 27009–L, 27221–L, 27224–L to 27226–L, incl., 27530–L, 28197–L, 28198–L, 30522–L, 30523–L, 33706–L, 33707–L, 41973–L, 41974–L, 48408–L.)

LIBELS FILED: Between April 1 and May 29, 1952, District of Massachusetts, Northern District of California, Northern and Western Districts of New York, Western District of Washington, District of Columbia, Western District of Michigan, Western District of Louisiana, Middle District of Pennsylvania, Northern District of Iowa, Eastern District of Virginia, Northern District of Illinois, and Middle District of North Carolina.

ALLEGED SHIPMENT: Between the approximate dates of September 26, 1951, and March 28, 1952, by the Hope Co., from St. Louis, Mo., and East St. Louis, Ill.

PRODUCT: 1,146 dozen bottles of *Hope mineral tablets* at Boston and Springfield, Mass.; Alameda, Oakland, San Francisco, Watsonville, San Mateo, Burlingame, and Sacramento, Calif.; Amsterdam, Schenectady, and Rochester, N. Y.; Seattle, Wash.; Washington, D. C.; Grand Rapids, Mich.; Shreveport, La.; Harrisburg, Pa.; Cedar Rapids, Iowa; Alexandria, Va.; Chicago, Ill.; and Durham and Greensboro, N. C.

RESULTS OF INVESTIGATION: Various representations concerning the conditions for which the product was intended were published in advertisements contained in local newspapers at the places where the product was located. These advertisements were printed on instructions of, and from mats furnished by, the Hope Co.

LABEL, IN PART: "Hope Mineral Tablets with B-Vitamins Dietary Supplement. Each tablet contains 20 mgm. Iron; ½ mgm. Vitamin B_1; 1 mgm. Vitamin B_2; and 5 mgm. Niacin. Also contains traces of other minerals (elements) extracted from a natural clay" or "Forty Hope Mineral Tablets Dietary Supplement Each tablet contains 20 mgm. of Iron and traces of other minerals (extracted from a natural clay) plus ½ mgm. Vitamin B_1, 1 mgm. Vitamin B_2, 5 mgm. Niacin and ½ mcg. Vitamin B_{12}."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of rheumatism, headaches, weak kidneys, arthritis, stomach ailments, neuritis, dizzy spells, nervousness, bloating, acids, toxins, lack of energy, lack of vitality, sleepless nights, underweight, irritability, bad complexion, bad breath, frequent rising at night, vague pains, digestive disturbances, weakness, weak sexual powers, poor appetite, poor lactation, weakened reproductive powers, paleness, general run-down condition, heartburn, stomach gas, weak back, lumbago, decaying teeth, failing eyesight, and dullness, which were the conditions for which the article was intended. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the labeling of the portion of the product at Cedar Rapids, Iowa, namely, clippings which were from local newspapers and which accompanied the article, was false and misleading. The labeling contained statements which represented and suggested that the article was an effective treatment for vague pains, bad breath, headaches, digestive disturbances, dizzy spells, lack of vitality and energy, paleness, numbness, heartburn, stomach gas, bad complexion, tiredness, listlessness, irritability, general run-down feeling, nervousness, lack of appetite, and sleeplessness. The article was not effective for such purposes. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: Between May 12 and September 4, 1952. Default decrees of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3749. Adulteration and misbranding of tincture of belladonna and tincture of Hyoscyamus. U. S. v. Standard Drug Co., Inc., and Jacob Starr. Plea of guilty by corporation; plea of nolo contendere by individual. Fine of $500 against each defendant. (F. D. C. No. 32740. Sample Nos. 4823–L, 22774–L, 22775–L, 22931–L.)

INFORMATION FILED: February 29, 1952, District of New Jersey, against Standard Drug Co., Inc., Newark, N. J., and Jacob Starr, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about August 31, 1950, and February 15 and April 5 and 26, 1951, from the State of New Jersey into the States of Massachusetts and New York.

LABEL, IN PART: "Tincture of Belladonna" and "Tincture of Hyoscyamus."

NATURE OF CHARGE: *Tincture of belladonna.* Adulteration, Section 501 (b), the article purported to be and was represented as "*Belladonna Tincture*," a drug, the name of which is recognized in the United States Pharmacopeia; and its strength differed from the official standard since the article yielded from each 100 cc. less than 27 mg. of the alkaloids of belladonna leaf, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "Tincture of Belladonna U. S. P." was false and misleading since it represented and suggested that the article was "*Belladonna Tincture*," as defined in the United States Pharmacopeia, whereas the article was not "*Belladonna Tincture*" as therein defined.

Tincture of Hyoscyamus. Adulteration, Section 501 (b), the article purported to be and was represented as "*Hyoscyamus Tincture*," a drug, the name of which is recognized in the United States Pharmacopeia; and its strength differed from the official standard since the article yielded from each 100 cc. less than 3.4 mg. of the alkaloids of *Hyoscyamus*, the minimum permitted by the standard. Misbranding, Section 502 (a), the label statement "Tincture of Hyoscyamus U. S. P." was false and misleading since it represented and suggested that the article was "*Hyoscyamus Tincture*," as defined in the United States Pharmacopeia, whereas the article was not "*Hyoscyamus Tincture*" as therein defined.

DISPOSITION: May 2, 1952. A plea of guilty having been entered by the corporation and a plea of nolo contendere by the individual, the court imposed a fine of $1,000 against each defendant. On July 2, 1952, the court reduced the fine against each defendant to $500.

3750. Adulteration and misbranding of procaine penicillin G in aqueous suspension. U. S. v. 20 Packages * * *. (F. D. C. No. 32386. Sample No. 10947–L.)

LIBEL FILED: January 3, 1952, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about February 13, 1951, from Atlanta, Ga.

PRODUCT: 20 packages, each containing 10 tubes, of *procaine penicillin G in aqueous suspension* at Chattanooga, Tenn. Analysis showed that the potency per tube varied from 208,000 units to 248,000 units.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement "Each Tubex contains 300,000 units crystalline procaine penicillin G" was false and misleading as applied to the article, the potency of which was less than that stated on the label.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 24, 1952. Default decree of condemnation and destruction.

3751. Adulteration of posterior pituitary injection. U. S. v. 45 Vials * * *. (F. D. C. No. 32513. Sample Nos. 25917–L, 26130–L.)

LIBEL FILED: February 11, 1952, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 15, 1951, by Gold Leaf Pharmacal Co., Inc., from New Rochelle, N. Y.

PRODUCT: 45 vials, each containing 10 cc., of *posterior pituitary injection* at Philadelphia, Pa.

LABEL, IN PART: "Sterile Solution Posterior Pituitary (obstetrical) 10 Units per cc. with Chlorobutanol (chloral Deriv.) 0.5%."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Posterior Pituitary Injection," a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since the United States Pharmacopeia provides that each cubic centimeter of *posterior pituitary injection* possesses an activity equivalent to 10 U. S. P. posterior pituitary units, whereas each cubic centimeter of the article possessed an activity equivalent to less than 10 U. S. P. posterior pituitary units.

DISPOSITION: March 25, 1952. Default decree of condemnation. The court ordered that the product be turned over to the Federal Security Agency.

3752. Adulteration of conjugated estrogen tablets. U. S. v. 885 Bottles * * *. (F. D. C. No. 32587. Sample No. 21235-L.)

LIBEL FILED: January 11, 1952, Western District of Texas.

ALLEGED SHIPMENT: On or about January 29, 1951, from St. Louis, Mo.

PRODUCT: *Conjugated estrogen tablets.* 885 100-tablet bottles at San Antonio, Tex. Analysis showed that the product contained a total amount of estrogenic steroids calculated to be 0.60 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Each tablet contains water soluble conjugated estrogens, naturally occurring, expressed as sodium estrone sulfate 1.25 mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: April 24, 1952. Default decree of condemnation and destruction.

3753. Adulteration and misbranding of Arvimin. U. S. v. 5 Cases * * *. (F. D. C. No. 33067. Sample No. 12091-L.)

LIBEL FILED: April 11, 1952, Southern District of Ohio.

ALLEGED SHIPMENT: On or about June 19, 1951, from Marion, Ohio.

PRODUCT: 5 cases, each containing 12 1-pound cans, of *Arvimin* at Cincinnati, Ohio. Analysis showed that the product contained approximately 16 percent of the declared amount of vitamin A and 50 percent of the declared amount of vitamin D_2.

LABEL, IN PART: "Arvimin Each 1 Lb. (453.6 Grams) Represents—Active Drug Ingredient—Sodium Arsanilate * * * 5.0 Grams Incorporated in a Nutritional Base Composed of * * * Vitamin A (U. S. P. Units) 300,000 Units – Vitamin D_2 (U. S. P. Units) 1,000,000 Units."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Each 1 Lb. * * * Represents * * * Vitamin A (U. S. P. Units) 300,000 Units – Vitamin D_2 (U. S. P. Units) 1,000,000 Units" was false and misleading as applied to the article, which contained less than those amounts of vitamins A and D_2.

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 23, 1952. Default decree of condemnation and destruction.

3754. Adulteration and misbranding of adhesive bandages. U. S. v. 39 Boxes * * *. (F. D. C. No. 33035. Sample No. 3617–L.)

LIBEL FILED: On or about April 10, 1952, District of Maryland.

ALLEGED SHIPMENT: On or about February 29, 1952, by Supreme First Aid Co., Inc., from New York, N. Y.

PRODUCT: 39 boxes, each containing 36 packages, of *adhesive bandages* at Baltimore, Md.

LABEL, IN PART: "Supreme Handy Adhesive Bands Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug, the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: May 6, 1952. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3755. Misbranding of liver injection. U. S. v. 371 Vials * * *. (F. D. C. No. 32948. Sample No. 37609–L.)

LIBEL FILED: March 12, 1952, Southern District of New York.

ALLEGED SHIPMENT: On or about September 13, 1951, by Armour Laboratories, from Chicago, Ill.

PRODUCT: 371 1-cc. vials of *liver injection* at New York, N. Y. Analysis showed that the product contained vitamin B_{12} activity equivalent to approximately 11 micrograms of cyanocobalamin per cubic centimeter.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Each cc. contains Vitamin B_{12} activity equivalent to 20 micrograms of cyanocobalamin" was false and misleading as applied to the article, which contained less vitamin B_{12} activity than that declared.

DISPOSITION: April 2, 1952. Default decree of condemnation. The court ordered that a portion of the product be delivered to the Food and Drug Administration and that the remainder be destroyed.

3756. Misbranding of Cystex, Romind, and Mendaco. U. S. v. 213 Packages, etc. (F. D. C. No. 32211. Sample Nos. 13865–L to 13867–L, incl.)

LIBEL FILED: December 11, 1951, District of Colorado.

ALLEGED SHIPMENT: On or about September 21, 1951, and possibly other dates about that time, by the Knox Co., from Newark, N. J.

PRODUCT: 213 $1.00-size packages and 144 $2.00-size packages of *Cystex*, 80 $1.00-size packages and 38 $2.00-size packages of *Romind*, and 69 $0.75-size packages, 26 $1.25-size packages, and 10 $2.50-size packages of *Mendaco*, at Denver and Englewood, Colo., together with proof sheets entitled "U. S. Cystex Series 800," "U. S. Romind Series 702," and "U. S. Mendaco Series 703," and tear sheets from the Denver Post issue of October 7, 1951.

Enclosed in the packages containing the drugs were one or more leaflets entitled "Directions for Use," "A letter to you from our president," and "For Your Family Medicine Chest."

*See also Nos. 3741, 3744, 3747–3750, 3753, 3754.

LABEL, IN PART: "Cystex * * * Each Tablet contains Acetophenetidin 1½ grains, Methanamine and Benzoic Acid," "Romind Each tablet contains: Sodium Salicylate, Acetophenetidin 1½ grains, Caffeine Alkaloid," and "Mendaco Each Tablet contains Potassium Iodine 2¼ gr., Extract Lobelia."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements borne on the package labels and in the accompanying leaflets, proof sheets, and newspaper tear sheets were false and misleading. These statements represented and suggested that:

The *Cystex* was an effective treatment for affections of the kidneys and bladder, tiredness, nervousness, backache and other aches, stiffness, rheumatic pains, protracted colds, swollen ankles, dizziness, and effects of over-eating or drinking, and it would delay the aging process and endow the user with vigor.

The *Romind* was an effective treatment for arthritis, rheumatism, neuritis, sciatica, fibrositis, lumbago, and soreness and stiffness, and it would remove uric acid from the body.

The *Mendaco* was an effective treatment for sinusitis, bronchitis, asthma, stubborn cough, and mucus congestion in the nasal sinuses.

The articles would not be effective treatments for the conditions referred to. They were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: March 21, 1952. Default decree of condemnation and destruction.

3757. Misbranding of Arthrid. U. S. v. 10 Bottles * * *. (F. D. C. No. 32942. Sample No. 14893-L.)

LIBEL FILED: March 12, 1952, Northern District of Oklahoma.

ALLEGED SHIPMENT: On or about August 28 and November 13, 1951, by Pacific Mineral Industries, from Hollywood, Calif.

PRODUCT: 10 100-tablet bottles of *Arthrid* at Tulsa, Okla. Partial analysis showed that the Colchicum present in the product yielded 0.16 mg. of colchicine per tablet; that the Lobelia present in the product yielded 0.15 mg. of alkaloids per tablet; and that no detectable amount of wintergreen oil or other salicylate was present.

LABEL, IN PART: (Bottle) "Arthrid A scientific blend of 22 rare imported and domestic natural herbs * * * Each tablet contains a * * * blend of the following herbs: Black Cohosh, Burdock, Chickweed, Colombo, Lobelia, Scullcap, Buckbean, Rest Harrow, Colchicum, Tamarac Bark, Bitter Root, Bearsfoot, Wintergreen, Sarsaparilla, Dandelion, Sassafras, Valerian Root, Juniper Berries, Cinchona Bark, Angelica Root, Saw Palmetto Berries, Buckthorn Bark."

NATURE OF CHARGE: Misbranding Section 502 (a), the name of the article "Arthrid" and certain statements on the label of the article were false and misleading. The name of the article and the statements represented and suggested that the article would rid the user of arthritis and that it was an adequate and effective treatment for arthritis and rheumatism. The article would not be effective for such purposes.

Further misbranding, Section 502 (a), the label statement "blend of 22 rare imported and domestic natural herbs" was misleading since the statement suggested that all of the 22 herbs listed were therapeutically or physiologically active, whereas such was not the fact; and, Section 502 (c), the information

required by law to appear on the label, namely, the common or usual name of each active ingredient, was not prominently placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use since the label failed to reveal which of the ingredients listed were therapeutically or physiologically active.

DISPOSITION: April 2, 1952. The consignee having appeared and filed a response which was in the nature of a waiver, judgment of condemnation was entered and the court ordered that the product be destroyed.

3758. Misbranding of Mer-I-Col iron tonic. U. S. v. 202 Bottles, etc. (F. D. C. No. 32543. Sample No. 10487–L.)

LIBEL FILED: February 25, 1952, Eastern District of Michigan; amended libel filed March 27, 1952.

ALLEGED SHIPMENT: On or about January 9, 1952, by the National Mer–I–Col Sales Co., from Columbus, Ohio.

PRODUCT: 202 8-ounce bottles and 34 1-pint bottles of *Mer–I–Col iron tonic* at Pontiac, Mich.

LABEL, IN PART: (Bottle) "Mer–I–Col Iron Tonic Active Ingredients Iron and Ammonium Citrates, Gentian Root, Thiamine Hydrochloride and a trace of Copper Sulfate (Iron Catalyst)."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the tear sheets from a local newspaper, were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for rheumatism, arthritis, neuritis, headaches, nervousness, acids, toxins, bloating, lack of vitality and energy, poor appetite, underweight, dizzy spells, indigestion, gas on stomach, dyspepsia, intense pain in the stomach and chest, wild heart palpitation, loss of weight, tissue, and strength, sour stomach, cramps, spitting up bits of half digested food and hot sour liquid, biliousness, sick headaches that last for days, constipation, yellowish complexion, painful, heavy, bloated feeling in lower stomach, worn-out feeling, sleeplessness, neuralgia and similar aches and pains, sharp pains over kidneys, frequent getting up nights, spots before the eyes, swelling of ankles, feet, and lower limbs, swollen capillary tubes, dull achy feeling across back, stiffness in the back and lower limbs, puffs or dark circles beneath the eyes, agonizing aches and pains, stomach disorders, weak kidneys, excess acid, infections, and aches and pains in arms, shoulders, fingers, hands, back, wrists, hips, and knees. The product was not an effective treatment for these diseases.

DISPOSITION: April 2, 1952. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

3759. Adulteration and misbranding of Magnatone Supplement. U. S. v. 28 Bags * * *. (F. D. C. No. 31952. Sample No. 10160–L.)

LIBEL FILED: October 31, 1951, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about June 21, 1951, by Magnatonic Products, Inc., from New Knoxville, Ohio.

PRODUCT: 28 50-pound bags of *Magnatone Supplement* at Hudson, Mich. Analysis disclosed that the product contained not more than one-half of the declared amounts of vitamins A and D.

LABEL, IN PART: (Bag) "Magnatone Supplement Minerals Vitamins for the Dairy Herd * * * Vitamin A (Carotene from Carrot Oil) 25,000 U. S. P. Units per lb., Vitamin D_2 (Irradiated Ergosterol * * * 10,000 U. S. P. Units per lb. * * * Ingredients Cottonseed Oil Meal; Linseed Oil Meal; Soybean Oil Meal, Dehydrated Alfalfa Meal; Distillers Solubles; Carrot Oil, Irradiated Ergosterol; Thiamine Chloride; Riboflavin; Nicotinic Acid; Calcium Carbonate; Steamed Bone Meal; Di-Calcium Phosphate; Tri-Calcium Phosphate (from defluorinated rock phosphate); Magnesium Carbonate; Magnesium Sulfate; Manganese Sulfate; Copper Sulfate; Iron Oxide; Zinc Sulfate; Potassium Iodide; Sodium Chloride (Salt); Cobalt Sulfate and Sodium Tetraborate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in accompanying booklets entitled "Magnatone Bulletin Volume 1," "Magnatone Health Products," and "The Magnatone Health Program," were false and misleading. The statements represented and suggested that the article was effective to prevent starvation and thereby assure completion of a normal life cycle, barring unnatural climatic conditions and accidents; to give vibrant health and full stamina and endurance; to confer disease resistance and perfect health; to remedy most livestock diseases, including mastitis, white scours of calves, shy breeding, and many other familiar disorders erroneously stated to be due to starvation; to condition quickly and rehabilitate the herd; to remedy anorexia (depressed appetite) and pneumonia; to revitalize quickly the digestive and metabolic systems of animals to operate at maximum capacity and efficiency; to assure freedom from disease and resistance to infections; to remedy injury to the nervous system; to insure against failure to grow; to treat yellow liver and anemia; to prevent death; to remedy fatty liver, cirrhosis of the liver, and disturbance of lactation and growth; to influence favorably production and growth of animals; to prevent sterility in animals of both sexes; and to effect phenomenal increases in milk production. The statements further represented that the article was effective against convulsions, kidney degeneration, sterility, abortions, birth of dead or weak calves, bone diseases, and paralysis. The article was not effective for the purposes represented.

The article was alleged also to be adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 25, 1952. Default decree of condemnation. The court ordered that the product be delivered to a Federal institution, for use as animal feed.

In attempting to execute the order of the court, the United States marshal found that the product under seizure had been returned to the State of Ohio, where it was fed to animals. Upon submission of these facts to the court, an order was entered on June 19, 1952, dismissing the libel.

3760. Misbranding of veterinary products. U. S. v. 22 Packages, etc. (F. D. C. No. 32548. Sample Nos. 29279–L to 29286–L, incl., 29290–L.)

LIBEL FILED: February 26, 1952, Eastern District of Washington.

ALLEGED SHIPMENT: On or about August 7 and November 19, 1946, September 3, 1947, June 23 and October 21, 1948, May 26, August 12, and November 13, 1950, January 18, March 22, and July 23, 1951, and other dates unknown, by the C. U. McClellan Laboratories Corp., from Los Angeles, Calif.

PRODUCT: 14 1¼-pound packages and 10 5-pound packages of *McClellan's Cow Compound;* 18 packages of *McClellan's Pullet Size Nic-Ka-Mal;* 15 packages of *McClellan's Adult Size Nic-Ka-Mal;* 28 2½-ounce packages and 41 8-ounce packages of *McClellan's Nicotine Krumbles;* 6 4-pound cartons of *McClellan's Phenothiazine Powder;* 14 4-ounce bottles, 24 8-ounce bottles, 18 32-ounce bottles, and 1 1-gallon bottle of *McClellan's Rex Liquid;* 92 1½-pound packages and 11 5-pound packages of *McClellan's Rex Poultry Powder;* and 24 1-quart bottles, 55 8-ounce bottles, and 44 16-ounce bottles of *McClellan's Inhalant,* at Spokane, Wash. A booklet entitled "1950 Price List" accompanied the products.

LABEL, IN PART: "McClellan's Cow Compound * * * Ingredients: Elecampane Root, Uva Ursi Leaves, Spearmint Leaves, Black Haw Bark, Ginger Root, Red Pepper, Aletris Root, Foenugreek Seed, Witch Hazel Leaves, Boneset Herb, Damiana Herb, Salt, Red Oxide of Iron, Epsom Salts"; "McClellan's Nic-Ka-Mal * * * Pullet Size Contains 100 7½-Grain Tablets [or "Adult Size Contains 100 15-Grain Tablets"] * * * These tablets contain Nicotine sulfate as Alkaloid 5%, Extract of Kamala 15%, Powdered Kamala 38%, Calcium Phosphate combined with inactive Acacia and Cerelose"; "McClellan's Nicotine Krumbles Active Ingredient Against Worms: Nicotine Sulfate expressed as Alkaloid for Nicotine 5%. Inert ingredients: Iron Sulfate, Rosin, Charcoal and Diatomaceous"; "McClellan's Phenothiazine Powder * * * Active Ingredient: Phenothiazine 100%"; "McClellan's Rex Liquid * * * Contains the following ingredients: Iron Sulfate, Epsom Salts, Glauber Salts, Salt, Lactic Acid, Benzoate of Soda, Quassia, Oil of Anise, Potassium Iodide, Red Pepper"; "McClellan's Rex Poultry Powder * * * Contains: Ground Limestone, Salt, Epsom Salts, Bone Meal, Sulfur, Iron Sulfate, Red Oxide of Iron, Manganese Sulfate, Charcoal, Salt Peter, Quassia, Anise Seed, Gentain, Soda Bicarbonate, Potassium Iodide, Copper Sulfate, Cobalt Chloride"; "McClellan's Inhalant * * * Contains: Oil of Camphor, Oil of Eucalyptus, Menthol Crystals, Thymol Crystals, Pine Oil, Mineral Oil."

NATURE OF CHARGE: *McClellan's Pullet Size Nic-Ka-Mal.* Misbranding, Section 502 (a), certain statements in the labeling of the article which represented and suggested that the article was effective to control large roundworm infestation of poultry and was beneficial in parasitism caused by tapeworms in poultry were false and misleading since the article was not effective and was not beneficial in the conditions represented; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions in its labeling for the treatment of pullet-size birds provided insufficient medication to effectively expel large roundworms from pullets.

McClellan's Nicotine Krumbles. Misbranding, Section 502 (a), certain statements in the labeling of the article which represented and suggested that the article was effective to control parasitism (large roundworms) in flocks of chickens and turkeys were false and misleading since the article was not effective for such purpose; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions in its labeling for the treatment of 200 pullets would supply insufficient medication to effectively expel large roundworms from 200 pullets.

McClellan's Cow Compound, McClellan's Adult Size Nic-Ka-Mal, McClellan's Rex Liquid, McClellan's Rex Poultry Powder, McClellan's Inhalant, and *McClellan's Phenothiazine Powder.* Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading. The statements represented and suggested that the *Cow Compound* was effective to restore cows to a normal healthy condition regardless of their condition before using the product; that the *Adult Size Nic-Ka-Mal* was effective to control large roundworm infestation in poultry and was beneficial in parasitism (tapeworms); that the *Rex Liquid* was effective for disease conditions of poultry characterized by diarrhea; that the *Rex Poultry Powder* was effective as a tonic and conditioner; that the *Inhalant* was effective against disease conditions of the throat and nostrils of poultry, and that its use as an inhalant or spray was an effective treatment of respiratory diseases of poultry; and that the *Phenothiazine Powder,* by removing cecal worms from poultry, was effective to prevent blackhead in turkeys, and that the article was effective to remove any variety of intestinal and stomach worms from poultry. The articles were not effective for the purposes and conditions stated and implied, and they were not capable of fulfilling the promises of benefit made for them.

DISPOSITION: April 14, 1952. Default decree of condemnation and destruction.

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PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

U. S. GOVERNMENT PRINTING OFFICE: 1952

D. D. N. J., F. D. C. 3761–3780 Issued December 1952

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3761–3780

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations by the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

CHARLES W. CRAWFORD, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 18, 1952.*

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3762–3764, 3766; omission of, or unsatisfactory, ingredients statements, Nos. 3761, 3777; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3761–3766; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3762, 3764–3766; labeling information not likely to be read and understood by the ordinary individual under customary conditions of purchase and use, No. 3768.

230654—52——1

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3761. Misbranding of sulfathiazole tablets. U. S. v. Hugh Allen (Hugh Allen, Druggist). Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 6 months. (F. D. C. No. 31562. Sample Nos. 3180–L, 3181–L.)

INFORMATION FILED: April 21, 1952, Northern District of West Virginia, against Hugh Allen, trading as Hugh Allen, Druggist, Petersburg, W. Va.

INTERSTATE SHIPMENT: From the State of Indiana into the State of West Virginia of quantities of *sulfathiazole tablets.*

ALLEGED VIOLATION: On or about May 10 and 15, 1951, while a number of tablets of the drug were being held for sale after shipment in interstate commerce, the defendant caused a number of such tablets to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the repackaged drug was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the repackaged drug; and, Sections 502 (f) (1) and (2), the labeling of the repackaged drug failed to bear adequate directions for use and adequate warnings against use in those pathological conditions where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: May 15, 1952. A plea of guilty having been entered, the court suspended the imposition of sentence and placed the defendant on probation for 6 months.

3762. Misbranding of Seconal Sodium capsules. U. S. v. Andrew Kolanowski. Plea of guilty. Fine, $100. (F. D. C. No. 32746. Sample No. 9420–L.)

INFORMATION FILED: April 25, 1952, Northern District of Illinois, against Andrew Kolanowski, an assistant pharmacist for Marshall Drugs, Chicago, Ill.

ALLEGED VIOLATION: On or about April 5, 1951, while a number of *Seconal Sodium capsules* were being held for sale at Marshall Drugs, after shipment in interstate commerce, the defendant caused a number of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: June 2, 1952. A plea of guilty having been entered, the court drug failed to bear adequate directions for use.

3763. Misbranding of Seconal Sodium capsules and dextro-amphetamine sulfate tablets. U. S. v. Joseph S. Pencek (Pencek Circle Pharmacy). Plea of guilty. Fine of $300, plus costs. (F. D. C. No. 32749. Sample Nos. 9641–L to 9644–L, incl.)

INFORMATION FILED: March 24, 1952, Northern District of Illinois, against Joseph S. Pencek, trading as Pencek Circle Pharmacy, Elmwood Park, Ill.

ALLEGED VIOLATION: On or about March 15 and 21 and April 3 and 17, 1951, while quantities of *Seconal Sodium capsules* and *dextro-amphetamine sulfate tablets* were being held for sale at the Pencek Circle Pharmacy, after shipment in interstate commerce, the defendant caused a quantity of the drugs to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: April 25, 1952. A plea of guilty having been entered, the court imposed a fine of $300, plus costs.

3764. Misbranding of dextro-amphetamine sulfate tablets, racemic amphetamine sulfate tablets, Seconal Sodium capsules, and Amytal tablets. U. S. v. Jacob Chubat (Chubat Pharmacy). Plea of guilty. Fine of $300, plus costs. (F. D. C. No. 32747. Sample Nos. 9404–L to 9409–L, incl.)

INFORMATION FILED: March 24, 1952, Northern District of Illinois, against Jacob Chubat, trading as Chubat Pharmacy, Chicago, Ill.

ALLEGED SHIPMENT: On or about March 21, April 3 and 11, and May 5, 10, and 16, 1951, while quantities of *dextro-amphetamine sulfate tablets, racemic amphetamine sulfate tablets, Seconal Sodium capsules,* and *Amytal tablets* were being held for sale at the Chubat Pharmacy, after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and dispensed without a prescription, which acts resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* and *Amytal tablets* contained chemical derivatives of barbituric acid, which derivatives have been found to be, and by regulations designated as, habit forming, and these drugs failed to bear labels containing the names, and quantities or proportions of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: April 14, 1952. A plea of guilty having been entered, the court imposed a fine of $300, plus costs.

3765. Misbranding of dextro-amphetamine sulfate tablets. U. S. v. Frank A. Ponzo (Ponzo's Drug Store). Plea of nolo contendere. Fine, $300. (F. D. C. No. 30616. Sample Nos. 21794–L to 21796–L, incl.)

INFORMATION FILED: August 22, 1951, Eastern District of Louisiana, against Frank A. Ponzo, trading as Ponzo's Drug Store, New Orleans, La.

INTERSTATE SHIPMENT: From the State of Pennsylvania into the State of Louisiana of quantities of *dextro-amphetamine sulfate tablets.*

ALLEGED VIOLATION: On or about January 26 and 29, 1951, while the drug was being held for sale after shipment in interstate commerce, the defendant caused quantities of the drug to be repacked and sold without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear labels containing the name and address of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use.

DISPOSITION: April 30, 1952. A plea of nolo contendere having been entered the court imposed a fine of $300.

3766. Misbranding of pentobarbital sodium capsules. U. S. v. Albert Blank (Eliot Square Pharmacy). Plea of guilty. Defendant fined $500 and sentenced to prison for 1 year; prison sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 32703. Sample No. 4857–L.)

INFORMATION FILED: April 3, 1952, District of Massachusetts, against Albert Blank, trading as Eliot Square Pharmacy, Boston, Mass.

ALLEGED VIOLATION: On or about September 18, 1951, while a number of *pentobarbital sodium capsules* were being held for sale at the Eliot Square Pharmacy after shipment in interstate commerce, the defendant caused a number of the capsules to be repacked and dispensed without a physician's prescription, which acts resulted in the repackaged drug being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drug failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor, and an accurate statement of the quantity of the contents.

Further misbranding, Section 562 (d), the repackaged drug contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the repackaged drug failed to bear a label containing the name, and quantity or proportion of

such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use.

DISPOSITION: April 18, 1952. A plea of guilty having been entered, the court imposed a fine of $500 and a sentence of one year in prison. The prison sentence was suspended, and the defendant was placed on probation for 2 years.

3767. Misbranding of Alberty products. U. S. v. Various Quantities * * *. Answer filed by claimant; Government's motion to strike certain portions of claimant's answer granted in part. Judgment for Government. Decree of condemnation. (F. D. C. No. 24186. Sample Nos. 6221–K to 6249–K, incl.)

LIBEL FILED: December 22, 1947, Western District of Pennsylvania.

ALLEGED SHIPMENT: Between the approximate dates of March 26 and November 10, 1947, by Alberty Food Products, from Hollywood, Calif.

PRODUCT: 44 cans of *Instant Alberty Food*, 46 cartons of *Alberty's Food Regular*, 17 bottles of *Alberty's vitamin B complex tablets*, 38 bottles of *Alberty's Vio-Min vitamin-mineral tablets*, 18 bottles of *Alberty Garlic and Vegetable Oil perles*, 36 bottles of *Alberty's Lebara pellets, Homeopathic*, 66 bottles of *Alberty's Lebara No. 2 pellets*, 12 bottles of *Alberty's Oxorin tablets*, 72 cartons of *Pandora tablets*, 72 bottles of *Alberty's Phosphate pellets*, 228 bottles of *Alberty Phloxo B tablets*, 36 bottles of *Recal tablets*, 36 bottles of *Alberty's Riol tablets*, 36 bottles of *Alberty's Sabinol pellets*, 6 cartons of *Alberty's Special Formula tablets*, 24 cartons of *Alberty's Vegetable Compound capsules*, 192 cartons of *Alberty's vitamin A (high potency) shark liver oil*, 60 bottles of *Alberty's vitamin B_1 with other B complex factors*, and 54 cartons of *wheat germ oil perles* at Pittsburgh, Pa.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in a large number of diseases, symptoms, and conditions for which the articles were prescribed, recommended, and suggested in booklets entitled "Dynamic Digests" and "Health Mysteries," which were disseminated and sponsored by and on behalf of the manufacturer, packer, and distributor of the articles.

Further misbranding (*Alberty's Lebara pellets, Homeopathic, Alberty's Lebara No. 2 pellets, Alberty's Phosphate pellets*, and *Alberty's Sabinol pellets*), Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use since the directions for use in the labeling failed to state the diseases, symptoms, or conditions for which the articles were directed to be taken.

DISPOSITION: Upon agreement by the parties, an order was entered on November 4, 1948, directing the removal of the case to the District of Columbia. Thereafter, the Alberty Food Products, claimant, filed an answer denying that the products under seizure were misbranded, and alleging certain defenses as described in the opinion set forth below. A motion to strike such defenses from the answer was filed by the Government, and on March 25, 1949, after consideration of the briefs and arguments of counsel, the court handed down the following opinion:

MOORE, *District Judge:* "On October 19, 1948, the government filed a libel against various quantities of articles alleged to be articles of drug and to have been shipped in interstate commerce by Alberty Food Products, a co-partnership. Various dates of shipment are alleged, beginning March 26, 1947, and ending November 10, 1947. The libel charges misbranding, within the meaning of Section 352 (f) (1) of the Federal Food, Drug and Cosmetic Act. (21 U. S. C. A. 301 et seq.) Different bases for the allegations of misbranding are alleged with reference to different shipments. They fall into three groups. As to one group of shipments, it is alleged that they were misbranded because they did not contain in the labeling a statement listing various diseases and ailments of the human body as to which they were claimed to possess therapeutic value, in two booklets disseminated by the manufacturer, packer and distributor, denominated respectively 'Health Mysteries' and 'Dynamic Digest.' Another group is alleged to be misbranded for lack of the same information in the labeling, but with reference to 'Dynamic Digest' alone. The third group is alleged to be misbranded, not only because its labeling contains no reference to the diseases for which claims are made in 'Health Mysteries' and 'Dynamic Digest,' but also because the labeling contains no directions for use other than a designated quantity and frequency of dosage.

"Alberty Food Products on December 2, 1948, filed its answer to the libel, setting up, among other defenses, (A) that Section 352 (f) (1) of the Act does not sustain the allegations of the libel for the reason, as claimant avers, that the provision that the labeling contain 'adequate directions for use' does not require that the labeling of a drug state the diseases or conditions of the body for which the drug when used as directed will be effective, nor does it require that the labeling of a drug state each of the diseases and conditions of the body for which the drug is advertised as a therapeutic treatment; (B) that the dissemination of the booklets 'Health Mysteries' and 'Dynamic Digest' has been abandoned by the claimant following cease and desist orders of the Federal Trade Commission heretofore issued against the claimant on the ground that the booklets contain false advertising; (C) that the labeling upon each of the articles prescribes maximum quantity and dosage, and therefore satisfies the requirements of Section 352 (f) (1) of the Act, and (D) that the booklet entitled 'Dynamic Digest' was not disseminated prior to August 15, 1947, whereas some of the articles alleged to be misbranded for lack of information in the labeling about diseases and ailments concerning which claims are made in 'Dynamic Digest' were alleged to have been shipped in interstate commerce prior to that date.

"The government has moved to strike the above defenses from the answer on the ground that they are insufficient in law, and on the further ground as to some of them that they are immaterial.

"The relevant portions of the Act, together with the interpretive regulation with reference thereto issued by the Commissioner of Food and Drugs on December 22, 1939, as amended April 10, 1941, are as follows:

> Section 352: "A drug or device shall be deemed to be misbranded * * * (f) Unless its labeling bears (1) adequate directions for use; * * *"
>
> Section 334: "(a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce * * * shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found * * *"
>
> 21 C. F. R. Cum. Supp. Section 2.106: "(a) Directions for use may be inadequate by reason (among other reasons) of omission, in whole or in part, or incorrect specification of:
>
> > (1) Directions for use in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer, or in such other conditions, if any there be,

for which such drug or device is commonly and effectively used; * * *"

"It is clear from the terms of the Food, Drug and Cosmetic Act, as well as from its legislative history, that Congress intended, insofar as the Act relates to drugs, to provide effective safeguards for the public in their use of such articles, by requiring that all drugs shipped in interstate commerce be labeled in such fashion that the consumer thereof shall be given all information reasonably necessary for the intelligent use of the drug in self-medication. H. R. 2139, 75th Cong., 3 Sess. p. 8.

"It is obvious that in the use of drugs for self-medication the health of the consumer may be endangered in any of three ways: First, if the drug is misbranded either by omission from the labeling of a statement of its ingredients, or by false statements in the labeling with reference to the contents of the package, or with reference to the efficacy of the drug in the treatment of certain diseases; secondly, if the drug is placed on the market with no mention in the labeling of any disease or ailment for which the manufacturer intends it to be used as a cure or palliative, while at the same time the manufacturer falsely advertises it to the public through other means as having therapeutic value in certain diseases; and, thirdly, if the labeling mentions some diseases or ailments for which the drug is claimed to be a remedy, while the manufacturer falsely advertises to the public by other means that it is a remedy for other and different diseases and ailments. The peril to public health from the first of these means is apparent from its mere statement, and Congress has provided protection against the danger in Section 352 (a) of the Act. It is perhaps not so clearly apparent from the other two means. Nevertheless the danger therein is real and substantial. Where no diseases or ailments whatever are mentioned in the label, if the consumer who purchases the product is one who is not aware of the advertised claims he is left to speculate without guide as to the diseases or conditions for which it is intended to be used, and therefore may use it for some condition in which it is neither effective nor intended to be so, but may be harmful. If the consumer is aware of the advertising, he is led to purchase the drug for self-medication in some disease or condition for which it is not effective, and may be hurtful. In the third situation, a consumer who has knowledge of the advertiser's claims may purchase the drug for use, not for an ailment specified in the labeling, but in some disease or condition for which the advertiser falsely claims it is efficacious, though not mentioned in the labeling; and in such case, if the advertiser's advice be followed, the result is the same as in the second situation. A purchaser is led into a form of self-medication which is of no benefit to him, which may be directly harmful, and which is further deleterious to his health because of the fact that it deters or prevents him from seeking other means of relief.

"The section of the statute under consideration must be construed in the light of the underlying Congressional purpose, and so as to give effect to the Act as a whole, if a reasonable construction can be arrived at which may accomplish that end.

"The words, 'adequate directions for use,' necessarily relate to some purpose which is to be served by the use, and that purpose must be consistent with the intent of the Act as a whole to protect the public health. For what purpose are drugs used? Obviously, as a remedy for some ailment of the body. It seems equally obvious that no drug can be said to contain in its labeling adequate directions for its use, unless every ailment of the body for which it is, through any means, held out to the public as an efficacious remedy be listed in the labeling, together with instructions to the user concerning the quantity and frequency of dosage recommended for each particular ailment. See the following unreported cases, cited in the government's brief: *United States* v. *150 pkgs.* * * * *Bush Mulso Tablets*, (E. D. Mo.) No. 4415, C. C. H. Food and Cosmetic Law Reports, § 7059; *United States* v. *516 cases* * * * *Nue-Ovo*, (S. D. Col.) No. 7418, C. C. H. Food, Drug and Cosmetic Law Reports, § 7091.

"It may be that compliance with this requirement, thus freeing the shipper from any liability under Section 352 (f) (1), would result in the drug being misbranded under Section 352 (a) of the Act; and doubtless this is the precise result which was intended in those cases where false and misleading advertising claims are made which are omitted from the labeling.

"Any other construction of Section 352 (f) (1) would provide the manufacturer and shipper with a convenient loophole through which he could evade the Act with resulting danger to public health. He need only include in the labeling either dosage directions alone, or with the addition of one or more bodily diseases or ailments for which he claims the drug is efficacious, and by a contemporaneous advertising campaign lead the public to believe that the drug is a remedy for a multitude of ailments. In such cases, if claimant's first and third defenses be good, there is no section of the Act which protects the public against the resulting harm.

"I am not impressed by the argument of counsel for claimant that the administrative interpretation hereinbefore set out sustains his construction of Section 352 (f) (1). Keeping in mind the Congressional intent, I am of opinion that the clear meaning of the Administrator in this interpretive regulation is that not only the dosage, but the disease or diseases for which such dosage is recommended or advertised, must appear in the labeling if the labeling is to be held to bear adequate directions for use. This conclusion finds support in the unreported case of *United States* v. *Colgrove*, (S. D. Cal.) cited in the government's brief as No. 5992, C. C. H. Food, Drug and Cosmetic Law Reports, § 7046, in which case the District Court granted an injunction restraining defendants from introducing into interstate commerce any product without a label bearing adequate directions for use of such product in the treatment of all ills for which it was advertised, which directions were to include the dosage to be taken in each of such conditions.

"Paragraphs (A) and (B) of claimant's first defense in the answer to the libel, and the third defense therein, will therefore be stricken as insufficient defenses.

"It will next be considered whether the alleged fact that the booklet, 'Dynamic Digest,' was not disseminated prior to August 15, 1947, if true, is a defense to the allegation that certain articles of drug which were shipped prior to that date were misbranded for lack of inclusion in the labeling of the names of the diseases and ailments for which they were recommended for use in 'Dynamic Digest,' together with directions for their use in such ailments. All but five of the articles of drug mentioned in the libel were advertised in both 'Health Mysteries' and 'Dynamic Digest,' with substantially the same recommendations and representations with respect to their remedial and curative qualities. One of the five shipments as to which the allegations are based solely on claims made in 'Dynamic Digest' was made after August 15, 1947. As to another of the five, the allegation of misbranding is based not only on claims made in 'Dynamic Digest,' but also on omission from the labeling of any directions for use other than mere prescription of the quantity and frequency of dosage. Therefore, the words 'but avers that "Dynamic Digest" was not disseminated by it prior to August 15, 1947,' appearing in Paragraphs 21, 22, 23, 27, 29, 33, 34, 35, 36, 38, 39, 41 and 42 of the fourth defense will be stricken as immaterial.

"This leaves for consideration three articles of drug advertised only in 'Dynamic Digest,' of which some shipments were made prior to August 15, 1947, with respect to which the sole basis of the libel is that claims of therapeutic qualities as to certain diseases were made in 'Dynamic Digest.'

"It is my opinion that the drugs in these particular shipments could not be said to be misbranded under the terms of Section 352 (f) (1) by reason of omission from the labeling of those diseases and ailments for which the drugs had not been held out in any way to the public as cures or palliatives prior to the respective dates of shipment. Therefore, I will overrule the motion to strike the words 'but avers that "Dynamic Digest" was not disseminated by it prior to August 15, 1947,' appearing in Paragraphs 25, 31, and 43, of the fourth defense, insofar as they relate to those shipments of the three articles of drug last referred to made prior to August 15, 1947. Of course, the government may still prevail in its charge that these drugs were misbranded, if it can prove that it was the intention of the shipper at the time of shipment to make the claims for them which were afterwards made in 'Dynamic Digest'; but this proof cannot rest alone on the fact that 'Dynamic Digest' was subsequently disseminated.

"Finally, with reference to the second defense, namely, that dissemination of the booklets 'Health Mysteries' and 'Dynamic Digest' has been abandoned by the claimant, it does not appear from any of the pleadings that the booklets are

alleged to have been abandoned prior to the shipping date of any of the shipments which were seized. Their abandonment after shipments were made could constitute no defense to the allegation of misbranding, since under the Act misbranded drugs may be seized at any time after they are shipped in interstate commerce. 21 U. S. C. A. 334. Therefore, the motion to strike the second defense will be sustained as the pleadings now stand. However, I believe that if the answer were amended to show that the abandonment of dissemination of the booklets took place before the date of some or all the shipments, this would be a good defense, at least conditionally, as to those shipments which were subsequent to the abandonment. I say conditionally, because it is only to the extent that the abandonment of such dissemination creates an inference that the shipper did not intend, when it shipped the drugs in interstate commerce, that they be used for the treatment of the diseases named in the booklets, that the abandonment can be said to be effective as a defense. The government might introduce evidence to show that, notwithstanding such abandonment, it was still the intention of the shipper that the drugs be used for the treatment of the diseases mentioned in the booklets; but in the absence of such proof, it is my opinion that the abandonment would warrant the inference that there was no intent to misbrand as to drugs shipped thereafter.

"One of the arguments advanced by claimant is that since the Federal Trade Commission has been given authority by Congress to prevent false advertising, whereas such authority has been denied to the Food and Drug Administration, it should be held that the Federal Trade Commission is the only agency of government which can operate in this field. But it is well settled that the action of either of these agencies—that of the Food and Drug Administration relative to misbranding, and that of the Federal Trade Commission relative to false advertising—is not the exclusive remedy afforded to the government in a case where both misbranding and false advertising are present. In other words, the fact that the government may seize an article because it is misbranded does not prevent the Federal Trade Commission from issuing a cease and desist order with reference to false advertising concerning that article: and conversely, the issuance of a cease and desist order does not prevent the government from proceeding against the article because of the misbranding. *United States* v. *5 Cases of Capon Springs Water*, (C. C. A. 2, 1946) 156 F. (2d) 493; *United States* v. *Research Laboratories*, (C. C. A. 10, 1942) 126 F. (2d) 42, Cert. denied 317 U. S. 656.

"An order may be entered in accordance with this opinion."

On April 14, 1949, pursuant to the above opinion, an order was entered granting in part and denying in part the Government's motion to strike. On January 9, 1950, a request for admissions of certain facts was served by the Government upon the claimant, pursuant to Rule 36 of the Rules of Civil Procedure; and on March 20, 1950, an answer to the request was submitted. Thereafter, motions for summary judgment were filed on behalf of the Government and the claimant. On February 5, 1951, it appearing to the court that there existed no genuine issue as to any material fact, an order was entered denying the claimant's motion and granting the Government's motion for summary judgment, and ordering that the products be condemned and destroyed.

An appeal taken to the United States Court of Appeals for the District of Columbia was dismissed on or about June 18, 1952. On July 1, 1952, the products were destroyed.

3768. Misbranding of Vigorettes. U. S. v. 169 Dozen Bottles, etc. (F. D. C. No. 33251. Sample Nos. 8418-L, 8419-L.)

LIBEL FILED: May 15, 1952, Western District of New York.

ALLEGED SHIPMENT: Between the approximate dates of March 24 and May 1, 1952, from Cleveland, Ohio.

PRODUCT: 672½ dozen bottles of *Vigorettes* at Buffalo, N. Y., in possession of Vigorettes, Inc., together with a number of display posters entitled "Now! New! More Potent Vigorettes" which were printed locally. The bottles were of various sizes, containing 30, 60, 90, 200, and 500 "capsulettes."

LABEL, IN PART: (Bottle) "Vigorettes Improved Added Potency Each Vigorette Capsulette Contains: Vitamin B_1 (Thiamine Hcl.) USP 5 mg., Vitamin B (Riboflavin) USP 5 mg., Vitamin B (Pyridoxine Hydrochloride) 0.5 mg., Vitamin C (Ascorbic Acid) 30 mg., Niacinamide USP 50 mg., Calcium Pantothenate 10 mg., Folic Acid USP 0.1 mg., Liver Desiccated NF 275 mg., Ferrous Gluconate (Equivalent to 20 mg. of Iron) 194.4 mg., Choline (Bitartrate) 15 mg., Inositol 10 mg., Vitamin B_{12} (from strepomyces fermentations) 5 mcg., dl-Methionine 5 mg., Vitamin E 31 U., Iodine (from potassium iodide) 0.1 mg., Manganese (from manganese glycerophosphate) 1 mg., Cobalt (from cobalt sulfate) 0.1 mg., Zinc (from zinc sulfate) 1 mg., Magnesium (from magnesium sulfate) 2.5 mg., Potassium (from potassium sulfate) 2 mg., Molybdenum (from sodium molybdate) 0.2 mg. * * * Dosage Adults: 1 or 2 Capsulettes daily."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the posters accompanying the article were false and misleading. The statements represented and suggested that the article when used as directed was effective in the treatment of anemia, nervousness, weakness, tiredness, poor digestion, heart trouble, migraine headaches, insomnia, tooth decay, pernicious anemia, coronory disease, and sterility, and that use of the article would insure better blood, steadier nerves, stronger and longer life, resistance to disease, better growth, healthy heart, healthy gums and teeth, pliant joints, healthy skin, good digestion, healthy liver, and proper muscle growth and tissue function. The article when used as directed was not effective in the treatment of such conditions, and it was not capable of fulfilling the promises of benefit made for it.

Further misbranding, Section 502 (c), the information required by Section 502 (e) (2), to appear on the label of the article, namely, the common or usual name of each active ingredient contained therein, was not prominently placed on the label with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use since it failed to distinguish between the active and inactive ingredients; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which the article was intended.

The article was alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 16, 1952. Vigorettes, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency, and that the posters be destroyed.

3769. Misbranding of Scientific Massage Modality devices and Stim-U-Lax Junior devices. U. S. v. 19 Devices, etc. (F. D. C. No. 32237. Sample Nos. 16400-L, 16401-L.)

LIBEL FILED: On or about December 18, 1951, Western District of Missouri.

ALLEGED SHIPMENT: On or about April 4 and August 1, 1951, by the John Oster Manufacturing Co., from Milwaukee, Wis.

PRODUCT: 19 *Scientific Massage Modality devices* and 5 *Stim-U-Lax Junior devices* at Kansas City, Mo., together with a number of leaflets entitled "Oster Scientific Massage Modality * * * 360–A" and "Oster Stim-U-Lax Junior * * * 644" and a booklet entitled "Massage An Aid to Better Health * * * A–20095."

Each device consisted of a metal and rubber frame containing an electric motor which was mounted with an eccentric bearing at one end and a spring-held bearing at the other end, so that rotation of the motor caused the device to have a rapid vibratory motion.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklet and leaflets accompanying the devices were false and misleading. The statements represented and suggested that the devices were effective for providing better health; curing aches and pains; providing healing power; treating the sick and disabled; stimulating the circulation in the deeper tissues; helping remove and discharge waste products and tissue debris; soothing tense nerves; treating acute inflammation, sprains of joints, fractures of bones, and chronic inflammation; relaxing muscle spasm, as well as spasm of vessel walls; increasing the flow of blood and lymph; increasing local metabolic activity; promoting tissue repair; treating edema and obstructed venous return; helping to remove exudate and waste products; improving local nutrition; maintaining the general health of the body during a period of enforced fatigue; treating nerve prostration; maintaining the vitality and flexibility of parts that must be kept at rest for a long time; raising the blood pressure and increasing the amount of red and white blood cells; increasing the urine; stimulating the whole body; improving sleep; removing the waste products of fatigue; reducing swellings; stretching adhesions; loosening scars; loosening joints; acting on organs under the ribs; aiding nutrition of the tissues; discharging waste products and fatigue acids; soothing the nerves; relieving tension; helping the wasted body of convalescence to return to normal; treating overindulgence, lack of sleep, the "morning after" feeling, head and chest colds, and sinus conditions; reducing; keeping the teeth healthy; treating insomnia, nervousness, and headaches; providing vigor for elderly people; curing rheumatism; treating cramps; improving the condition of the scalp and hair; treating fractures, sprains, and dislocations; restoring muscle tone; reducing edema; treating sciatica and neuritis; giving health; and treating tired muscles, taut nerves, and a fagged worn-out feeling. The devices were not effective in the treatment of the conditions stated and implied, and they were not capable of fulfilling the promises of benefit made for them. The devices were misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, arthritis, migraine headaches, rheumatism, cerebral hemorrhage, and polio, which were the conditions for which the devices were recommended orally by Mrs. Helen Moyer on behalf of the John Oster Manufacturing Co. The devices were misbranded in these respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 2, 1952. The John Oster Manufacturing Co., claimant, having consented to the entry of a decree, judgment of condemnation was

entered and the court ordered that the devices be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The above-mentioned booklet and leaflets subsequently were destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3770. Supplement to notices of judgment on drugs and devices, No. 3652. U. S. v. Woodard Laboratories, Inc., and Dean D. Murphy and John L. Sullivan. Judgment of trial court affirmed on appeal. (F. D. C. No. 30053. Sample Nos. 29794–K, et al.)

Following the imposition of the sentences against the defendants, as reported in notices of judgment on drugs and devices, No. 3652, an appeal was taken by the defendants to the United States Court of Appeals for the Ninth Circuit. On August 29, 1952, the following opinion was handed down by that court, affirming the judgment of the lower court:

ORR, *Circuit Judge:* "This is an appeal from judgments of conviction on an information charging appellants with violation of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. A. § 301 et seq. Appellant Woodard Laboratories packaged and shipped in interstate commerce certain drugs manufactured by Crest Laboratories. Appellants Murphy and Sullivan are, respectively, president and general manager of Woodard Laboratories. The information charged the appellants in ten counts with five interstate shipments of alpha-estradiol tablets whose strength was below that declared on the labels; each shipment was the basis for two counts; one relating to adulteration and one to misbranding. 21 U. S. C. A. §§ 331 (a), 351 (c), and 352 (a). The District Court, sitting without a jury, found each of the defendants guilty on the five counts relating to adulteration. A total fine of $2500 was imposed upon Woodard and a total fine of $500 was imposed on each of the individual defendants.

"The tablets in question are shipped under the trade name 'Estrocrine' and contain alpha-estradiol, a female sex hormone which is dispensed only by or on the prescription of a physician. Samples of the tablets were subject to laboratory analysis by the Food and Drug Administration; the results of these assays led directly to the filing of the information. A drug distributor has an absolute liability for adulterated and misbranded drugs that he introduces into interstate commerce. 'Balancing relative hardships, Congress has preferred to place it on those who have at least the opportunity of informing themselves of the existence of the conditions imposed for the protection of the consumers before sharing in the illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.' United States v. Dotterweich, 320 U. S. 277, 285 (1943). The appellants contend, however, that the evidence was insufficient to sustain the judgment. A determination of this question requires a brief summarization of the evidence.

"Two witnesses testified for the Government. They are outstanding authorities in the general field of pharmaceutical chemistry and both have had a large experience in the study of estrogenic hormones.[1] They described in detail the methods of assay used in determining whether the Woodard tablets contained the 22 mcgs. of alpha-estradiol their labels represented the tablets to possess.

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[1] Jonas Carol has been a chemist with the United States Food and Drug Administration for 21 years, and is chief of the Synthetic Branch of the Division of Pharmaceutical Chemistry. Practically all of his work has been in the analysis of drugs and in the development of methods for their analysis; during the past six years he has been engaged almost exclusively in developing methods for analysis of estrogenic hormones.

Dr. Daniel Banes has been a chemist with the Food and Drug Administration since 1939, specializing in drug analysis since 1940, and doing his chief work since 1948 on the analysis of estrogenic drug preparations.

"Witness Carol used what is known as the infra-red method of analysis in order to double check on the United States Pharmacopoeia, known as U. S. P., method used by the other Government chemists in analyzing samples from the shipments in question. He testified that special procedures were used in an effort to insure complete extraction of the alpha-estradiol from the tablets. Carol stated that his assays disclosed that the amount of alpha-estradiol present per tablet ranged from 23% to 68% of the amount declared on the label.

"Witness Carol also described the results of assays conducted by his associate, Dr. Edward Haenni, upon samples from three of the shipments by means of the U. S. P. method[2] which had been developed by Mr. Carol and his associates. Dr. Haenni's assays indicated that the alpha-estradiol content of the tablets in these three shipments ranged from 32% to 63% of the amount declared on the label. Witness Carol further testified that he had previously tested a number of samples of other commercially prepared alpha-estradiol tablets containing 22 mcgs. by means of the U. S. P. method with successful results.

"Dr. Banes, using the U. S. P. method, assayed samples taken from all five of the shipments in question. He then conducted further special experimental procedures not required by the U. S. P. method, involving additional extractions and the use of a simulated tablet mix, to verify his findings which indicated that the alpha-estradiol content of the tablets ranged from 30% to 73% of the stated amount. Dr. Banes also testified that in the development of the U. S. P. method of assay the developing chemists made certain the method would extract all but a minute portion of the alpha-estradiol in the particular tablets regardless of the ratio of the drug to excipients.

"The appellants do not dispute the fact that less than the purported 22 mcgs. of alpha-estradiol was extracted from the tablets packaged, as measured by the U. S. P. procedure. Their argument is that the U. S. P. method, while perhaps effective in analyzing tablets of greater potency, is inaccurate and unsuitable in extracting alpha-estradiol when combined with the large mass of excipients present in these particular tablets.[3]

"A Mr. Galindo, Vice-President of Crest Laboratories, identified worksheets which purported to indicate meticulous care by Crest in the manufacture of the tablets. He testified that an average of 5% more alpha-estradiol was used than necessary to make a tablet containing 22 mcgs. of the drug. The worksheets were said to show the process of manufacture, step by step, and disclose that the required amount of the drug was placed in the tablets.

"Dr. C. E. P. Jeffreys, consulting chemist and technical director of Truesdail Laboratories, testified that he was asked by Woodard to run an assay on tablets from the shipments in question. Using the U. S. P. procedure, he was able to extract only 8.1 to 9.5 mcgs. of alpha-estradiol from the tablets.[4] Dr. Jeffreys stated that he believed the U. S. P. method of assay did not extract all of the alpha-estradiol present in tablets of such low potency because of adsorption to the solid surface of the excipients, and was thus not a suitable method.[5]

"Dr. Hoyt and Dr. Sobel, associated with the Cedars of Lebanon Hospital, testified to certain experiments conducted at the request of the appellants subsequent to the hearing before the Food and Drug Administration. These experiments, involving assays upon pure estradiol, tablets specially manufactured by Crest to insure the presence of a stated quantity of alpha-estradiol,

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[2] The United States Pharmacopoeia is designated an official compendium by the Federal Food, Drug and Cosmetic Act. 21 U. S. C. A. § 321 (j). U. S. P. XIV first officially recognized alpha-estradiol and provided a method for assay of the drug November 1, 1950. See p. 227. The U. S. P. assay procedure involves a series of extractions in a prescribed method followed by use of a colorimeter to determine the amount of alpha-estradiol extracted.

[3] The Woodard tablets were represented to contain a ratio of 22 parts alpha-estradiol to 324,000 parts of excipients.

[4] Other laboratories retained by the appellants, with the exception of the Adam Laboratories, also were unable to extract and measure the purported 22 mcgs. by means of the U. S. P. method. The Adam Laboratories found no deficiencies in one of a series of assays it conducted and suggested that this discrepancy was caused by some fault in the manufacturing process.

[5] Mr. Don C. Atkins, another witness for the appellants, also testified to a belief that the U. S. P. method was unsuitable, although his testimony tended to suggest that the excipients would cause an artificially high reading of alpha-estradiol.

and tablets containing all the excipients of the usual tablet manufactured by Crest into which Dr. Hoyt and Dr. Sobel personally added certain quantities of alpha-estradiol, were asserted to demonstrate that it was not possible by the use of the U. S. P. method to recover all of the alpha-estradiol when it was held in excipients of the sort that were found in the Woodard tablets.

"The usual rule to be followed in determining the sufficiency of evidence to sustain a judgment is well settled. 'It is not for us to weigh the evidence or to determine the credibility of witnesses. The verdict of a jury must be sustained if there is substantial evidence, taking the view most favorable to the Government, to support it.' Glasser v. United States, 315 U. S. 60, 80 (1942). See Banks v. United States, 147 F. 2d 628 (9th Cir. 1945). However, the appellant strongly urges that the Government's case is founded upon circumstantial evidence, and that therefore the proper test of whether the evidence is sufficient to sustain the judgment depends upon whether all of the substantial evidence is as consistent with a reasonable hypothesis of innocence as with guilt; if it is, the judgment must be reversed. Karn v. United States, 158 F. 2d 568 (9th Cir. 1946); McCoy v. United States, 169 F. 2d 776 (9th Cir. 1948). We find it unneccessary to decide whether the nature of the inference required to logically connect the experimental procedures used by the Government chemists with the factual issue of adulteration requires a characterization of the evidence as circumstantial. Even if we were to concede that the evidence of results obtained in the assays should be regarded as circumstantial, it cannot be said as a matter of law that all the substantial evidence is as consistent with a reasonable hypothesis of innocence as with guilt. The fact that some of the evidence admitted is consistent with innocence is not determinative of the sufficiency of the evidence. Ferris v. United States, 40 F. 2d 837 (9th Cir. 1930). Witness Galindo's worksheets contained a number of discrepancies and omissions which the District Court reasonably could consider on the question of credibility. Although Dr. Hoyt, Dr. Sobel and Dr. Jeffreys testified that their experiments led them to believe the U. S. P. method of assay was unsuitable in these circumstances, the District Court properly could choose to believe instead the testimony of the Government scientists who developed the assay procedure and who testified that the procedure will enable extraction and measurement of alpha-estradiol in tablets of any potency. Substantial evidence is '* * * such relevant evidence as a reasonable mind might accept as adequate to support a conclusion * * *.' N. L. R. B. v. Columbian Co., 306 U. S. 292, 300 (1939). The testimony of witnesses Carol and Banes was substantial and cannot be said to have been as consistent with a reasonable hypothesis of innocence as with guilt.

"Appellants did not attempt to prove the potency of their tablets by some procedure other than the U. S. P. method of assay,[6] they object to the Court's treatment of this as being in the nature of a failure of proof. It is argued that since alpha-estradiol was recognized and the method of assay appeared in an official compendium, U. S. P. XIV, seven months prior to the filing of the information, the determination as to the strength of the drug could be made only according to the official method of assay set forth in the compendium. 21 U. S. C. A. § 351 (b) states that when a drug is recognized in an official compendium the '* * * determination as to its strength, quality or purity shall be made in accordance with the tests or methods of assay set forth in such compendium * * *.' Appellants could be held criminally responsible only in the event the drugs were adulterated at the time of their interstate shipment. 21 U. S. C. A. § 331 (a). See Pasadena Research Laboratories v. United States, 169 F. 2d 375, 380 (9th Cir. 1948), cert. den., 335 U. S. 853. Since at the time of such interstate shipments between August 22, 1949, and May 25, 1950, the United States Pharmacopoeia did not officially recognize alpha-estradiol tablets, 21 U. S. C. A. § 351 (b) is inapplicable. The information in fact was based upon 21 U. S. C. A. § 351 (c), which defines adulteration in those situations where § 351 (b) does not apply, *and which is silent as to*

[6] Dr. Hoyt, the appellants' own witness, testified that the alpha-estradiol content of the tablets could have been measured by other assay procedures:

"Q. (The Court) Had they been submitted to you, could you have made an analysis and determined the exact amount of alpha-estradiol in those tablets, using any method you cared to?

"A. I think it could be done—I think perhaps by biological assay it could be done, if not by the U. S. P. method. I am sure it could be done."

the method of determination. There was therefore no restriction upon the method of assay to be employed, although of course the subsequently adopted U. S. P. method was entitled to great weight. As the District Court itself noted, the most direct way for the appellants to have impeached the U. S. P. method of assay would have been for them to have attempted to prove the potency of their tablets by some other assay method.

"Judgment affirmed."

3771. Adulteration and misbranding of vitamin C and vitamin B_1. U. S. v. 330 Vials, etc. (F. D. C. No. 33076. Sample Nos. 17714–L, 17717–L.)

LIBEL FILED: April 16, 1952, Southern District of California.

ALLEGED SHIPMENT: Between January 1944 and January 1950, from Detroit, Mich.

PRODUCT: 330 2-cc. vials of *vitamin C* and 90 10-cc. vials of *vitamin B_1* at Los Angeles, Calif. Analysis showed that the 330-vial lot contained approximately 85.8 mg. of ascorbic acid per each 2 cc. and that the 90-vial lot contained approximately 76 mg. of vitamin B_1 per each 1 cc.

LABEL, IN PART: "2 cc. size vitamin C Each 2 cc. contains 100 mg. Ascorbic Acid" and "10 cc. size vitamin B_1 (thiamine chloride) Each cc. contains vitamin B_1 100 mg. (equivalent to 33,000 international units)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strengths of the articles differed from those which they purported or were represented to possess.

Misbranding, Section 502 (a), the statements on the label of the *vitamin C* "Each 2 cc. contains 100 mg. Ascorbic Acid" and on the label of the *vitamin B_1* "Each cc. contains vitamin B_1 100 mg. (equivalent to 33,000 international units)" were false and misleading as applied to the articles, which contained less than those amounts of ascorbic acid and vitamin B_1, respectively.

The articles were adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 8, 1952. Default decree of condemnation and destruction.

3772. Adulteration and misbranding of vitamin B complex. U. S. v. 13 Cases * * *. (F. D. C. No. 33116. Sample No. 31517–L.)

LIBEL FILED: May 2, 1952, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about February 18, 1952, by Delta Laboratories, from Inglewood, Calif.

PRODUCT: 13 cases of *vitamin B complex* at St. Louis, Mo. Analysis showed that the product contained approximately 69 percent of the declared amount of thiamine hydrochloride (vitamin B_1).

LABEL, IN PART: "B Complex with B_{12} & Folic Acid per Vial * * * Thiamine HCL. 10 Mg. * * * Size 10 CC. Units 450 Lot No. 1007."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 10 mg. of thiamine hydrochloride per vial.

Misbranding, Section 502 (a), the label statement "per Vial * * * Thiamine HCL. 10 Mg." was false and misleading as applied to the article, which contained less than 10 mg. of thiamine hydrochloride per vial.

DISPOSITION: May 27, 1952. Default decree of condemnation and destruction.

3773. Adulteration and misbranding of adhesive bandages. U. S. v. 35 Boxes, etc. (and 1 other seizure action). (F. D. C. Nos. 32481, 32523. Sample Nos. 980–L, 981–L, 1266–L, 1267–L, 37768–L, 37769–L.)

LIBELS FILED: On or about February 7, 1952, Middle District of North Carolina and Eastern District of New York.

ALLEGED SHIPMENT: On or about December 17 and 28, 1951, by Medical Fabrics Co., Inc., from Paterson, N. J.

PRODUCT: 309 boxes each containing 100 *adhesive bandages*, and 182 boxes each containing 50 *adhesive bandages*, at Lexington, N. C., and Brooklyn, N. Y.

LABEL, IN PART: "2" x 2¾" 'Presso' Patch [or "Round Presso Patch"] Sterilized Plain Pad Elastic Adhesive Occlusive Dressing," "3" x 3" 4-Wing 'Presso' Joint Patch Elastic Adhesive Dressing * * * Sterilized," and "1" x 3" 'Presso-plast' Elastic Stick Pad * * * Sterilized."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Adhesive Absorbent Bandage," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading as applied to the article, which was not sterile but was contaminated with living micro-organisms.

DISPOSITION: April 30, 1952. Medical Fabrics Co., Inc., having appeared as claimant and the libel proceedings having been consolidated for hearing before the United States District Court for the Eastern District of New York, and the claimant having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reprocessing, under the supervision of the Federal Security Agency.

3774. Adulteration of hypodermic syringes. U. S. v. 132 Syringes, etc. (F. D. C. No. 32366. Sample No. 10817–L.)

LIBEL FILED: December 20, 1951, Southern District of Indiana.

ALLEGED SHIPMENT: On or about November 9, 1951, by E. Miltenberg, Inc., from New York, N. Y.

PRODUCT: 132 2-cc. size, 9 5-cc. size, and 9 10-cc. size *hypodermic syringes* at Indianapolis, Ind. Examination showed that approximately 25 percent of the syringes were defective in that the metal tip at the bottom of the syringe was cracked, thereby permitting a substantial portion of the medication to escape through the crack when one attempted to inject the medication by pressing on the plunger.

LABEL, IN PART: "Miltex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported to possess since its quality was impaired by a crack in the metal tip, permitting leakage of the medication to be injected by use of the article.

DISPOSITION: July 28, 1952. Default decree of forfeiture. The court ordered that a portion of the article, namely, 63 of the syringes which were found to be

not defective, be delivered to a State agency, and that the remainder of the article be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS *

3775. Misbranding of Gramer's Sulgly-Minol. U. S. v. 213 Bottles, etc. (and 1 other seizure action). Judgment for claimant; reversed on appeal. Decree of condemnation and destruction. (F. D. C. Nos. 28497, 28679. Sample Nos. 50094–K, 50095–K, 68846–K.)

LIBELS FILED: January 3 and 10, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about October 15 and 17 and November 22, 1949, by Walter W. Gramer, from Minneapolis, Minn.

PRODUCT: 366 4-ounce bottles of *Gramer's Sulgly-Minol* at Seattle and Mount Vernon, Wash., together with a number of leaflets entitled "Arthritis Hundreds Claim Its Grip Broken" and "A Light Should Not Be Hidden." Examination disclosed that the product consisted essentially of a lime and sulfur solution.

LABEL, IN PART: "Gramer's Sulgly-Minol A Solution of Sulphur, Glycerine, Sulphurated Lime and Isopropyl Alcohol 6%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the leaflets accompanying the article were false and misleading. The statements represented and suggested that the article was effective as a treatment, cure, and preventive for rheumatism and arthritic conditions and as a treatment for boils and acne. The article was not effective for such purposes.

DISPOSITION: Walter W. Gramer, claimant, filed answers to the libels on May 16, 1950, denying that the product was misbranded and affirmatively alleging that the issues raised by the libels had been adjudicated previously in his favor in a criminal case filed by the Government against him in the District of Minnesota. On May 22, 1950, an order was entered consolidating the two libel actions. Thereafter, a motion to strike the affirmative defense from the defendant's answers was filed by the Government, and on August 22, 1950, this motion was denied. Following this denial, a motion for summary judgment was made by the claimant on the ground that there was no genuine issue as to any material fact and that claimant was entitled to a judgment as a matter of law.

On September 11, 1950, the court granted the claimant's motion for summary judgment. An appeal was taken by the Government to the United States Court of Appeals for the Ninth Circuit, and on September 28, 1951, the following opinion was handed down by that court:

STEPHENS, *Circuit Judge:* "A criminal action brought by the United States against Walter W. Gramer in a federal district court in Minnesota in 1949 charged Gramer, claimant herein, with the introduction into interstate commerce of misbranded drugs in violation of the Federal Food, Drug, and Cosmetic Act.[1] After a plea of not guilty was entered, a trial on the merits was had and the district judge, sitting without a jury, adjudged claimant not guilty.

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*See also Nos. 3768–3773.

[1] Title 21, U. S. C. A. § 301, et seq.

"In January, 1950, two libels were filed by the government in the District Court for the Western District of Washington, against separate subsequent shipments of the same preparation of drugs as was involved in the Minnesota federal district court, for seizure and condemnation pursuant to provisions of the same act.[2] The cases were consolidated since the articles proceeded against and the charges were the same in both cases. It was undisputed that the contents of the bottles, the accompanying literature, the labeling, and all of the material issues raised were the same as those involved in the prior 1949 criminal action.

"Claimant's motion for summary judgment was granted for the reason that the issues raised by the government in the cause were adjudicated in favor of Gramer in the prior criminal action. Appeal is taken from the judgment of dismissal. Claimant contends that Coffey v. United States, 1886, 116 U. S. 436, requires an affirmance of the judgment below.

"In the Coffey case, the government sought to forfeit certain property for the reason that there had been a failure to comply with the laws regulating distilled spirits. The conduct upon which the seizure was based was the same as that alleged in a prior criminal information which had resulted in a verdict and judgment of acquittal. The Supreme Court held that while the proceeding to enforce the forfeiture against the res was a proceeding in rem and a civil action and that the prior action was a criminal proceeding, yet irrespective of the difference in burden of proof involved, the act had been put in issue and determined against the United States, and therefore the judgment of acquittal operated to bar any statutory punishment denounced as a consequence of the existence of the same facts.

"Subsequent decisions of the Supreme Court have strictly limited the operation of the Coffey rule, but the case has never been expressly overruled. True, in United States v. La Franca, 1931, 282 U. S. 568, the Supreme Court held that a civil action to recover tax penalties under the National Prohibition Act was barred by a prior conviction based on the same transactions as the taxes. But at the same time, in Various Items of Personal Property v. United States, 1931, 282 U. S. 577, the Supreme Court held that an action to forfeit certain distillery property was not barred by a prior conviction for the same transaction set forth in the libel as a basis for the forfeiture. While convictions were had in the two cited cases, acquittal was the result in the instant case.

"In Helvering v. Mitchell, 303 U. S. 391, decided in 1938, the question for decision was whether assessment and collection of an income tax fraud penalty was barred by the acquittal of the defendant under the same act for a wilful attempt to evade and defeat the tax. The Court of Appeals had ruled that Coffey v. United States, supra, and United States v. La Franca, supra, required it to treat the penalty as barred by the prior acquittal in the criminal action.

"The Supreme Court held that the difference in degree of the burden of proof in criminal and civil cases precluded application of the doctrine of res judicata. Since the fraud assessment was held to impose a civil administrative sanction to prevent the withholding of information by taxpayers, and not a criminal penalty, it was held not to place the defendant twice in jeopardy for the same offense, and not within the rule of the Coffey case.

"In United States ex rel. Marcus v. Hess, 1943, 317 U. S. 537, a statutory action providing that those who defraud the government by certain prohibited acts should 'forfeit and pay' to the United States $2,000 and double the amount of damages, was held not barred by the fact that the defendant had been previously indicted for the same acts and on a plea of nolo contendere, fined $54,000. The court relied upon Helvering v. Mitchell, supra, and indicated that the question was one of statutory construction.

"We need not dwell upon the problem of whether or not the Coffey case, even if limited to its facts, is still the rule in federal courts.[3] The expressions

[2] Title 21, U. S. C. A. § 334 (a).

[3] Consult: Stone v. United States, 1897, 167 U. S. 178; Murphy v. United States, 1926, 272 U. S. 630; United States v. National Association of Real Estate Boards, 1950, 339 U. S. 485. But see: United States v. Zucker, 1896, 161 U. S. 475; United States v. A Lot of Precious Stones and Jewelry, 1905, 6 Cir., 134 F. 61; United States v. Rosenthal, 1909, 5 Cir., 174 F. 652; Sierra v. United States, 1916, 1 Cir., 233 F. 37; United States v. 2180 Cases of Champagne, 1926, 2 Cir., 9 F. 2d 710; Stanley v. United States, 1940, 6 Cir., 111 F. 2d 898; United States v. One De Soto Sedan, 1950, 4 Cir., 180 F. 2d 583; United States

of the Court of Appeals for the Third Circuit in United States v. One Dodge Sedan, 1940, 3 cir., 113 F. 2d 552, 553, adequately covered our views on that subject when it stated that '* * * only the shibboleth of "stare decisis" has saved it from express repudiation.' A consideration of the subsequent holdings of the Supreme Court, discussed above, lead us to the conclusion that in the case before us neither the judicial doctrine of res judicata nor the constitutional mandate against double jeopardy operates to prevent the action here involved.

"RES JUDICATA. Where a right, question or fact has been put in issue and determined by a court of competent jurisdiction, as a ground of recovery, it cannot again be disputed in a subsequent suit between the same parties or their privies. Southern Pacific R. Co. v. United States, 1897, 168 U. S. 1, 48. But the Supreme Court has held that neither the doctrine of res judicata nor the rule of the Coffey case has application to a situation where there has been an aquittal on a criminal charge followed by a civil action requiring a different degree of proof.[4] Helvering v. Mitchell, 1938, 303 U. S. 391.

"Hence, since the prior action by the government was criminal in nature, while the cause before is civil, the doctrine of res judicata does not operate to make the acquittal a bar. Helvering v. Mitchell, supra.

"DOUBLE JEOPARDY. The principle behind the double jeopardy provision of the Fifth Amendment to the United States Constitution is that when a person has been acquitted on the merits the government shall not prosecute him a second time for the same offense. United States v. Oppenheimer, 1916, 242 U. S. 85. Since it is admitted that the libels filed herein did not seek to condemn the same shipment of preparation which was involved in the prior criminal action it is immediately apparent that there is no question of double jeopardy involved. This factor also distinguishes the case from our opinion in National Surety Co. v. United States, 1927, 9 Cir., 17 F. 2d 369, which case must be read with more recent expressions of the Supreme Court in mind. In addition, the Supreme Court has held in the Various Items of Personal Property case, supra, that a proceeding in rem to forfeit property used in committing an offense is not punitive in character, and therefore is not barred by a prior conviction for a criminal offense involving the same transactions. This would seem especially true in a condemnation proceeding under the Federal Food, Drug, and Cosmetic Act, where the purpose is not to punish the owner of the goods but to protect the public health. Ewing v. Mytinger & Casselberry, 1950, 339 U. S. 594; Hipolite Egg Company v. United States, 1911, 220 U. S. 45.

"If the Coffey case is to be considered as the law its doctrine, if taken to rule the instant case, would lead to great governmental limitation and public harm. An acquittal, even through wholly inadequate proof of violation of the Food, Drug, and Cosmetic Act, could practically stop the government from preventing the sale of a most harmful or wholly ineffective nostrum. Extension of the Coffey rule would not be justified unless clearly required.

"There is no doubt that the trial court was faced with a delicate question and, in the necessity of ruling promptly, committed error, which requires the judgment to be,

"Reversed and the cause remanded."

On May 7, 1952, the case having been remanded to the district court and the claimant having stipulated that the product might be destroyed, judgment of condemnation was entered and the court ordered that the product be destroyed.

3776. Misbranding of Gramer's Sulgly-Minol. U. S. v. 103 Bottles, etc. (F. D. C. No. 29674. Sample No. 78537–K.)

LIBEL FILED: August 15, 1950, Western District of Washington; amended libel filed September 21, 1950.

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v. Seattle Brewing & Malting Co., 1905, D. C. Wash., 135 F. 597; United States v. Gully, 1922, D. C. N. Y., 9 F. 2d 959; United States v. 119 Packages, More or Less, of Z-G-Herbs XXX No. 171, Double Strength, 1936, D. C. N. Y., 15 F. Supp. 327.

[4] This is not a case of successive libel proceedings involving the same issues as in Geo. H. Lee Co. v. United States, 1930, 9 Cir., 41 F. 2d 460. See Southern Pacific Co. v. Van Hoosear, 1934, 9 Cir., 72 F. 2d 903.

ALLEGED SHIPMENT: On or about June 29, 1950, by Walter W. Gramer, from Minneapolis, Minn.

PRODUCT: 103 4-ounce bottles of *Gramer's Sulgly-Minol at* Bellingham, Wash., together with a number of leaflets entitled "Walter W. Gramer Co. Manufacturers of Gramer's Sulgly-Minol" and "Arthritis . . . Hundreds claim It's Grip Broken" and a number of circulars entitled "A Light Should not be Hidden."

RESULTS OF INVESTIGATION: Investigation disclosed that the source of the leaflets entitled "Walter W. Gramer Co. Manufacturers of Gramer's Sulgly-Minol" was unknown and that the other leaflets and circulars were printed in Bellingham, Wash.

LABEL, IN PART: "Gramer's Sulgly-Minol A Solution of Sulphur, Glycerine, Sulphurated Lime and Alcohol 6%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the leaflets and circulars accompanying the article were false and misleading. The statements represented and suggested that the article was effective as a treatment, cure, and preventive for rheumatism and arthritic conditions and as a treatment for boils and acne. The article was not effective for such purposes. The article was alleged to be misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: May 7, 1952. Default decree of condemnation and destruction.

3777. Misbranding of Sobertabs. U. S. v. 50 Vials * * *. (F. D. C. No. 32963. Sample No. 3834–L.)

LIBEL FILED: On or about March 18, 1952, District of Maryland.

ALLEGED SHIPMENT: On or about November 23, 1951, by the Amlo Co., from Chicago, Ill.

PRODUCT: 50 vials of *Sobertabs* at Baltimore, Md., together with a number of display cards headed "Sober-Up Fast" and a number of leaflets entitled "For Really Fast Relief."

Analysis showed that each tablet of the article contained acetophenetidin, 40 milligrams; citrated caffeine, 271 milligrams; niacinamide, 12 milligrams; and thiamine hydrochloride.

LABEL, IN PART: (Vial) "12 Sobertabs * * * Contents: Acetophenetidin, Niacinamide, Caffeine Citrate, Thiamine Hydrochloride."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Sobertabs" and other statements on the vial label and accompanying display cards and in the leaflets were false and misleading since they represented and suggested that the article was an adequate and effective treatment for acute alcoholism and all of its manifestations, whereas the article was not an adequate and effective treatment for those conditions.

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the quantity or proportion of acetophenetidin contained therein.

DISPOSITION: April 10, 1952. Default decree of condemnation and destruction.

3778. Misbranding of cider vinegar. U. S. v. 12 Cases, etc. (F. D. C. No. 32565. Sample Nos. 23423–L, 23430–L.)

LIBEL FILED: March 7, 1952, Southern District of New York.

ALLEGED SHIPMENT: In the latter part of the year of 1951 and the early part of the year of 1952, from Sterling, Mass.

PRODUCT: 38 cases, each containing 24 1-pint bottles, and 1 case, containing 8 1-quart bottles, of cider vinegar at New York, N. Y., together with a number of pamphlets entitled "Sterling True Cider Vinegar for Sterling Health."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the pamphlet accompanying the articles were false and misleading. The statements represented and suggested that the article would maintain good health and restore health when impaired by many types of sickness; that it would promote vigorous health, reduce overweight, and neutralize the effects of prolonged physical and mental work; that it would offset chilling of the body by cold, emotional upsets, worry, and the effects of foods and drugs that produce an alkaline reaction of the urine, which effects are the background on which sickness develops; that it would correct menorrhagia; that it would cause blood from cuts to clot rapidly; that it would help to prevent and cure the common cold and help to normalize the body chemistry; that it would prevent sickness and maintain an acid reaction of the urine; that it would lessen putrefactive bacteria and improve the health of the digestive tract; that it would be effective for athlete's foot, poison ivy, sore throat, hay fever, and canker sores; and that it would prevent sunburn and enable one to better withstand summer heat. The article would not be effective for such purposes.

The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 22, 1952. Default decree of condemnation. The court ordered that the product be distributed to charitable institutions and that the pamphlets be destroyed.

3779. Misbranding of Air-Ozone device. U. S. v. 34 Devices, etc. (and 4 other seizure actions). (F. D. C. Nos. 32537, 32570 to 32573, incl. Sample Nos. 16576–L, 32696–L to 32699–L, incl.)

LIBELS FILED: March 13 and 17, 1952, District of Kansas and Southern District of Illinois.

ALLEGED SHIPMENT: On or about August 2, October 17, November 10, and December 11, 1951, and January 2 and 12, 1952, and other dates which are unknown, by the Air-Ozone Co. of Arizona, from Tucson, Ariz., and by Clarence A. Yackley, an agent of the company, from Phoenix, Ariz.

PRODUCT: 34 *Air-Ozone devices* and a number of booklets entitled "Ozone Therapy," "Ozone For Better Health," and "Ozone God's Gift to Humanity" at Wichita, Virgil, Sabetha, Gridley, Newton, Fort Scott, and Lamont, Kans., and Peoria, East Peoria and Peoria Heights, Ill.

Each device consisted of a group of 8 glass tubes connected together electrically to a control box. When the device was plugged into an electrical outlet and put in operation, the tubes would glow and emit light energy of various wave lengths, with production of ozone in the surrounding air.

LABEL, IN PART: "Air-Ozone * * * Ozone Generator * * * Air-Ozone Company of Arizona * * * Tucson, Arizona."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklets accompanying the article were false and misleading. The statements represented and suggested that the device would assist health, prevent disease, and act as a specific in many diseases; that it was effective for adenitis, swelling of the breasts, angina pectoris, alopecia, falling of the hair, arthritis, asthma, arteriosclerosis, backache, biliousness, bronchitis, bursitis, colitis, colds, sore chest, constipation, dandruff, deafness, erysipelas, earache, eczema, high blood pressure, indigestion, jaundice, leucorrhea, mumps, nervousness, pleurisy, prostate trouble, pneumonia, pelvic disturbances, psoriasis, quinsy, sore throat, rheumatism, rectal disturbances, sleeplessness, sinus trouble, tuberculosis, varicose veins, and wrinkles; that it would prevent radiation disease and germ disease; that it was effective for severe skin burn, eye injury, kidney disturbances, and heart attack; that it was effective to build health, promote longevity, relieve all kinds of disease, and prevent cancer; and that it was effective in the treatment of carbon monoxide poisoning, diabetic ulcer, and shingles. The device was not capable of fulfilling the promises of benefit made for it, and it was not effective for the purposes stated and implied.

DISPOSITION: April 10 and May 19, 1952. Default decrees of condemnation. The court ordered that the devices be delivered to the Food and Drug Administration.

3780. Misbranding of Therm-Massage infrared heat applicators and hair and scalp kits. U. S. v. 221 Cartons, etc. (F. D. C. No. 32216. Sample Nos. 22851–L, 22852–L.)

LIBEL FILED: December 6, 1951, Southern District of New York.

ALLEGED SHIPMENT: On or about September 7 and 10, 1951, by Sibert & Co., from Newark and Fair Lawn, N. J.

PRODUCT: 221 cartons each containing 1 *Therm-Massage infrared heat applicator* and 27 *hair and scalp kits*, at New York, N. Y., together with a number of circulars headed "Amazing New Scientific Invention Uses Powerful Infra-Red heat Plus Massage" and "Now! You can help to stop Baldness" and a scroll headed "The Famous Sibert Hair and Scalp Conditioner."

The *Therm-Massage infrared heat applicator* consisted of two pieces of molded bakelite, one serving as a handle and the other containing an electrically heated coil. The *hair and scalp kit* was a combination package containing 1 *Therm-Massage infrared heat applicator*, 2 small scalp massagers, and 1 jar of a salve.

RESULTS OF INVESTIGATION: The circulars were shipped with the consignment of devices which was shipped on September 10, 1951. Some of the circulars were displayed in the dealer's window with the products, and others were retained to be given to purchasers inquiring about the products. The scroll was made by the dealer and was displayed in his window.

LABEL, IN PART: (Carton) "Infra-Red Therm-Massage Heat Applicator"; (kit) "Hair and Scalp Conditioner Infra-red Heat-Massage Method"; and (jar) "Sibert Hair and Scalp Emollient."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circulars accompanying the devices were false and misleading since the device was not effective in the treatment of the conditions stated and implied and was not capable of fulfilling the promises of benefit made for it: (Circulars entitled "Amazing New Scientific Invention Uses Powerful Infra-Red Heat plus massage!") "Amazing New Scientific Invention Uses Powerful Infra-Red Heat plus massage! Therm-Massage Infra-Red Heat Applicator Wonderful Relief Comfort for – sinus – sprains * * * leg cramps * * * colds – backache – rheumatism – aching muscles – arthritis – stiff neck – aching joints – neuritis – foot cramps * * * Grateful Users Say. 'My sinus was relieved the first night I used your New Heat Applicator.' Mrs. R. 'It gave me the only relief I have from sinus pain.' Mrs. J. 'It has helped me with a strained left leg.' Mrs. B. Heat Massage Those Pains Away! If you suffer from aches and pains due to * * * toothaches, etc., that need soothing heat and massage, try this amazing new scientific invention. Discover How 'Therm Massage' relieves and relaxes * * * aching nerves * * * After I retire I use it about 20 minutes, then I rest all night. Before I got one of these I had to sleep in a rocking chair * * *"; (circulars entitled "Now! You can help to Stop Baldness * * *") "Now! You can help to Stop Baldness! Dandruff! * * * Excessive Falling Hair! With the New Sibert Hair & Scalp Conditioner * * * We have letters from users who also report that Sibert's Home Kit Has Grown Hair! * * * By the Infra Red Heat Massage Method * * * Both men and women have experienced amazing results with this easy to do 3-step treatment which gave them healthy hair * * * The dry gentle heat of Sibert's applicator * * * awakens dormant 'seeds' in the scalp, thus encouraging them to grow hair once more * * * Sibert's applicator also brings new blood to the scalp to add nourishment to the hair * * * Sibert's sensational new method which by conscientious and persistent use will promote and stimulate handsome, healthy hair * * *"; and (kit label) "Amazing New Hair & Scalp Conditioner Infra-Red Heat-Massage Method Scientists state that hair will continue to grow as long as the hair follicle remains healthy and a proper blood supply is fed to the Papilla. We believe that in many bald or partially bald people the Hair Follicles are still alive (possible just dormant) even though no hair is growing from them. * * * Only Nature Can Grow Hair. Science Can Help. We believe this to be a sensible scientific approach." The device was misbranded in the above respects when introduced into and while in interstate commerce.

Misbranding (hair and scalp kits), Section 502 (a), the statement "The Famous Sibert Hair & Scalp Conditioner Helps Stop Baldness" appearing on the scroll accompanying the kits was false and misleading since the kits were not effective to help stop baldness. The kits were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 1, 1952. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3761 TO 3780

PRODUCTS

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

[1] (3767, 3775) Seizure contested. Contains opinion of the court.
[2] (3770) Prosecution contested. Contains opinion of the court.

[2] (3770) Prosecution contested. Contains opinion of the court.

U. S GOVERNMENT PRINTING OFFICE: 1932